

## Creating Value. Living Values.



**Biotest AG** 

2008 Annual Report

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## 2008 at a glance

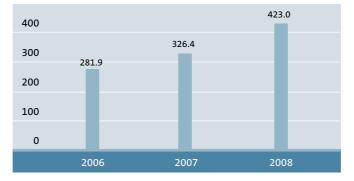
Biotest Group		2008	2007	Change %
Revenue	€ million	423.0	326.4	29.6
thereof: Germany	€ million	113.0	105.3	7.3
Rest of World	€ million	310.0	221.1	40.2
thereof: Plasma Proteins	€ million	339.5	247.0	37.4
Medical Diagnostics	€ million	45.2	44.3	2.0
Microbiologial Monitoring	€ million	38.3	35.1	9.1
EBITDA	€ million	81.8	54.9	49.0
EBIT	€ million	55.6	38.5	44.4
Profit before tax	€ million	40.5	30.2	34.1
Profit before tax in % of sales		9.6	9.3	_
Retained earnings attributable to equity holders of Biotest AG	€ million	25.7	15.5	65.8
Structure of expenses by nature:				
– Cost of materials	€ million	143.6	92.6	55.1
– Staff cost	€ million	115.4	83.7	38.9
<ul> <li>Research and development</li> </ul>	€ million	43.7	34.5	26.7
thereof: Biotherapeutics	€ million	16.6	14.2	16.9
<ul> <li>Research and development in % of sales</li> </ul>		10.3	10.6	_
Capital expenditure:				
<ul> <li>Property, plant and develop- ment and intangible assets</li> </ul>	€ million	36.5	32.0*	14.1
Financing:				
– Cash flow**	€ million	34.5	28.5	21.1
– Depreciation and amortisation	€ million	26.2	16.4	59.8
Equity	€ million	253.4	225.8	12.2
Equity in % of balance sheet total		42.8	42.1	_
Balance sheet total	€ million	592.0	536.7	10.3
Number of employees (full-time equivalents) as of year-en	d	1,952.3	1,726.5	13.1
Earnings per share	€	2.17	1.39	56.1
Earnings per preference share	€	2.23	1.45	53.8

\* in 2007, a further €119.9 million was added from the acquisition of the US Plasma Proteins business

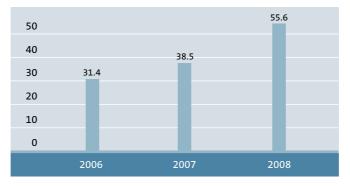
\*\* from operating activities

## Growth (2006 – 2008)

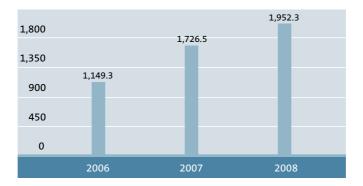
## Revenue of the Biotest Group in € million



### EBIT of the Biotest Group in € million



## Employees of the Biotest Group full-time equivalents



## LIVING OUR VALUES

Biotest products are of prime ethical importance. They save lives and give new hope to the chronically ill. They ensure reliable diagnostics in hospitals and laboratories and stand for the highest levels of purity in the production of drugs and food products.

Conscious of the responsibility this gives us, we direct our activities accordingly, in production as well as development, sales and raw materials procurement. Quality, user benefit, reliability and safety are our highest priorities.

These are the conditions which ensure that we are able to fulfil our mission and, at the same time, they form the basis for the long-term sustainable development of our company.



## WHY ARE WE DEVELOPING ANOTHER AGENT FOR THE TREATMENT OF RHEUMATISM, WHEN SO MANY OTHER TREATMENTS ARE ALREADY AVAILABLE?



# BECAUSE MILLIONS OF HUMAN BEINGS ARE IN URGENT NEED OF IT.

Rheumatoid arthritis is a serious disease of the immune system. Existing treatments bring no permanent relief to the majority of suffering patients and some have serious side effects. In around a quarter of all patients, available treatments have little or no effect. In Europe alone, several million people are affected.

## THE INTELLIGENT APPROACH

In the case of rheumatoid arthritis, the body's immune system attacks healthy tissue. Biotest is developing a new agent which inhibits this harmful reaction. New, effective and compatible treatments for indications with high medical demand. This is the aim of our research and development activities.

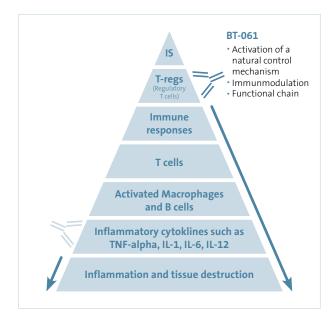
The immune system is a highly complex structure. The most varied messengers and cells steer the body's defence activities against viruses, bacteria and other organisms which cause disease. When this delicate balance is disturbed, these defence mechanisms may attack healthy tissue. This is termed an autoimmune disease by physicians.

One example of such diseases is rheumatoid arthritis (RA). Around 1% of the global population suffers from RA and in Germany alone, according to statistics published by the German Rheumatism League, 2,000 new cases are diagnosed every year. Those affected often suffer from intense pain as well as stiff and swollen joints, so that normal movement becomes severely inhibited. In the medium to long term, the disease can lead to complete failure of some joints. Up to now, RA has been considered incurable, and a remission – i.e. a comprehensive regression of the disease – can only be achieved in a maximum of 10% of patients.

One of the characteristic features of RA is hyperactivity of the messenger TNF-alpha. The abbreviation stands for tumour necrosis factor. Its function is to trigger the body's defences, but in the case of RA, uncontrolled release of this cytokine leads to chronic inflammation of the joints. In turn, TNF activity is itself controlled by T-regs (T regulatory cells). However, in RA patients, this control function is defective and the resulting uncontrolled TNF-alpha activity triggers a negative chain reaction in the body. Most of the approved RA drug treatments attempt to neutralise the TNF in order to interrupt the cycle of inflammatory reactions. However, this also suppresses normal immune system activity and can lead to severe infections or, in extreme cases, to lymphoma (cancer of the lymph nodes). In addition, a large proportion of patients show little or no reaction to these so called TNF antagonists.

Monoclonal antibody BT-061, currently under development at Biotest, is pursuing a fundamentally different strategy by activating the T-regs in the patient's body and in this way restoring the natural balance of the immune system. This interrupts the cycle of inflammatory eruptions without suppressing the body's normal immune defences (see diagram).

An early clinical study indicated that even low dosages are able to produce significant improvements in clinical symptoms, such as morning stiffness and swelling of the joints. Also in psoriasis, another autoimmune disease, the application of BT-061 in the context of a Phase I/IIa trial produced a sustained improvement in skin inflammations. "The findings to date are very encouraging and lead us to hope that we are on the road to an effective treatment of autoimmune diseases, such as rheumatoid arthritis and psoriasis," says Dr. Frank Osterroth, Head of Biotest's Biotherapeutics segment, fully aware that there are still considerable risks associated with a development project at such an early stage.



Mode of action of BT-061: the mAb intervenes at the upper end of the inflammatory cascade.

The fact that BT-061 constitutes a fundamentally new approach to treating an indication where medical need is high, makes it representative for all of Biotest's development projects in the Biotherapeutics segment. Given the high medical demand, we are making every effort to advance the development work as speedily as possible.

This is one of the reasons why, from the costly and timeconsuming clinical trials of Phase III onward, we are joining forces with one of the major pharmaceuticals who is a major player in the industry. As Dr. Osterroth explains: "If we intended to shoulder the entire development burden from start to approval, if at all, we could only manage to do this for just one of the three mAb candidates. Working together with a strong partner is not only the best possible approach to value-driven development of the preparations concerned, but also from the perspective of the patients waiting for treatments like BT-061."

#### The Biotest biotherapeutics pipeline

#### BT-061

Key indications	Rheumatoid arthritis, psoriasis
Mechanism of action	Activation of regulatory T-cells
Development status	Phase II clinical trials for both indications
Results to date:	Significant improvement of RA symp- toms in a pilot project, indications of very high level of effectiveness in the treatment of psoriasis in Phase I/IIa trial. Excellent tolerability in every case.
Medical demand:	High number of patients and no appro- ved remission treatment so far.
BT-062	
Key indication	Multiple myeloma (leukaemia)
Mechanism of action	mAb locks onto cancer cells, and therefore facilitates combination with
	highly effective toxins.
Development status	highly effective toxins. Phase I clinical trials
•	• ,

#### BT-063

Key indication	Systemic Lupus Erythematosus (SLE)
Mechanism of action	Inhibits harmful immuno-cytoki- nes, which play a key role in the progression of the disease.
Development status	Pre-clinical development, with cli- nical trials scheduled to commence before the end of 2009.
Medical demand	SLE incurable until now. There is no specific therapy.



## WHAT IS THE ADVANTAGE IF ONE OF OUR DRUGS CAN BE ADMINISTERED DIFFERENTLY?

Sunday

ctober 2008 hursday 14" Depension MEUSION 18-Friday Saturday

# FOR THE CHRONICALLY ILL, THE OPPORTUNITY OF A SIGNIFICANT IMPROVEMENT IN THEIR DAILY LIVES.

Patients suffering from immune diseases often take drugs throughout their lifetime. If these can be injected not only intravenously but also subcutaneously, patients can administer the drugs themselves and don't need to consult a physician for each injection. This would improve their quality of life and considerably reduce the burden on the health service.

## FOCUS ON PATIENT BENEFIT

After a liver transplantation necessitated by hepatitis B, throughout their lifetime patients need drugs to prevent the transplanted liver becoming re-infected with the virus. Hepatect<sup>®</sup>, the tried and tested treatment for this indication, is scheduled to be available as a self-medication product before the end of the year. Ongoing improvement of good products is a task to which Biotest is committed.

Chronic hepatitis B infections are among the main causes of liver failure and liver cancer. The sole possibility of a cure is for the patient to receive a liver transplantation. However, if a suitable organ can be found and if the delicate operation is a success, then the chances of survival are very good. In fact, the survival rate for patients surviving ten years after the operation is currently above 60%.

The critical factor is to prevent the transplanted liver from becoming re-infected by the hepatitis virus. If this occurs, the liver will become quickly inflamed, leading to liver failure.

Patients living with a transplanted liver after a serious hepatitis B infection consequently need to be treated with hyperimmunoglobulins for the rest of their lives. Hepatect<sup>®</sup> from Biotest is the leading preparation for this indication in Europe.

Until recently, Hepatect<sup>®</sup> could only be administered intravenously. Any infusion places patients under a certain amount of stress, especially if infusions are needed so frequently. Additionally, the regular consultations carried out by physicians are time-consuming, making this a costly form of treatment.

This is why we are working on developing Hepatect<sup>®</sup> for subcutaneous application, so that the preparation can be injected just beneath the surface of the skin.

Not only is this method much less stressful, it also has further advantages. Zutectra<sup>®</sup>, which is the name of the Hepatect<sup>®</sup> development, will be suitable for self-medication. Patients will be given ready-prepared syringes with which they can inject themselves. This is a procedure which has been tried and tested for a number of other indications, such as long-term insulin treatment for diabetes.

Approval for Zutectra<sup>®</sup> is expected before the end of the current year. We also aim to make the other long-term immunoglobulins gentler and more user-friendly. Another ongoing focus is maintaining the state-of-the-art safety of our preparations and adapting their profile accordingly (see box).

We are helped in this through our close cooperations, in some cases spanning decades, with leading hospitals, practices and research institutes working on the indications which our Plasma Proteins are used to treat.

#### **Plasma Proteins** Safety is the primary concern

The production of Plasma Proteins is subject to the most stringent safety requirements. Biotest has undertaken compliance with the standards of the PPTA association of manufacturers, whose regulations extend far beyond the statutory requirements.

The regulations cover the entire production spectrum, from plasma collection to end-product packaging. For instance, they prescribe that only plasma from so-called qualified donors may be used. This relates to individuals who donate regularly, often with only a few days between donations. This is possible because in case of plasmapheresis, only the plasma is harvested and all the other cellular components of the blood are reinfused directly back to the donor. Since donors give plasma on such a regular basis, their health is continually monitored. Before they are permitted to give plasma, their blood undergoes two test processes to check for HIV and hepatitis B and C infections.

Before the harvested plasma can be used for the production of any preparation, it has to be stored for at least 60 days. If, during this period, the donor develops an infection or other potential risks become apparent, the harvested plasma will be destroyed. The production process incorporates a series of steps to ensure that all viruses are eliminated. The raw material. semi-finished and end products are tested several times for contamination.

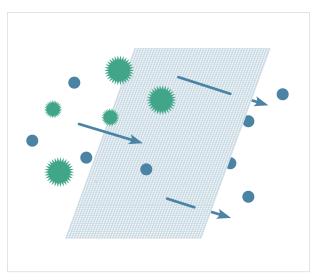
Biotest maintains a policy of ongoing adaptation of its own processes to respond to state-of-the-art technical developments. The most recent example of this is the integration of nanofiltration in the production of the immunoglobulin Intratect<sup>®</sup>. By this process, Plasma Proteins which have already been purified undergo further filtration when they are pumped through a system of hollow fibres with pores measuring around 20 nanometres. Most known viruses get caught in these pores.

Compliance with the regulations is regularly verified by the health authorities as well as by the PPTA. Biotest is one of five companies in the world entitled to use the PPTA quality seal.



the Q-SEAL mark.

#### Nanofiltration in the production of Intratect<sup>®</sup>



Nanofiltration is an additional safety step. Most know viruses get caught in the pores of the filters.



## WHEN DOES A GOOD IDEA BECOME AN INNOVATION?



# WHEN IT OFFERS MORE: MORE SAFETY, MORE EFFICIENCY, MORE VALUE.

Drug manufacturers must check their facilities regularly for any signs of contamination by particles or viruses and the results of these tests must be precisely recorded. By introducing intelligent solutions aimed at automatisation, manufacturers can achieve significant cost savings. However, even more important is the increased safety of the production processes.

## THE RIGHT IDEAS

In many cases, the process of monitoring air and workplace cleanliness and generating the associated documentation has remained a manual one. Not only is this inefficient, but it also carries a high risk of errors. Based on decades of experience and a profound understanding of customer needs, Biotest has developed a solution to the problem.

The paperless laboratory is about as far from reality as the paperless office, at least when it comes to the microbiology labs of the pharmaceutical, cosmetics and food industries. These companies are obliged to carry out a process of ongoing testing for germ and bacterial contamination and to document their findings. Even today, the process is usually carried out manually, with those responsible having to record the time and place of samplings on lists and then register the analysis results by hand. The data then has to be entered into computers and in many cases, data from several systems has to be consolidated.

With every piece of information passing through three or more pairs of hands, the process is not only timeconsuming, but costly. At every stage of this process the risk of errors, such as incorrect or incomplete data being recorded, increases. With HYCON ID and heipha Datamatrix-Code, Biotest last year launched two solutions to automate the process of registering data. With scanner-readable codes on the test media, paper and pens for recording sampling procedures are rendered obsolete.

By integrating heipha and HYCON products into a single piece of client software for planning, data processing and software analysis purposes, Biotest is now taking the next step. The company is developing a complete solution for automated hygiene monitoring for the pharmaceutical industry. All the data is accumulated in one system and where there is a need for data transfer, this occurs automatically. This makes the business of hygiene monitoring considerably more efficient, enhances safety and reduces the time needed to generate the results.

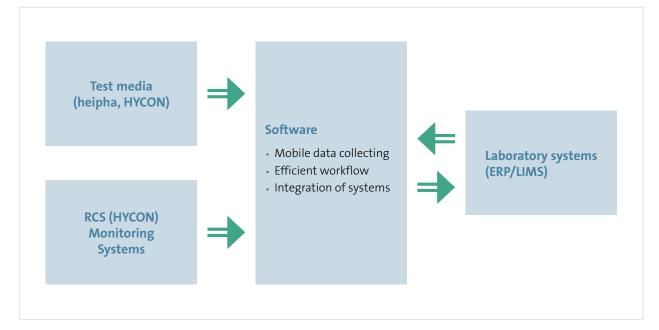
Processes and procedures, which are rather less than perfect and which up to now have lacked a solution, have been our inspiration. With a profound knowledge of the needs and wishes of our customers, we are able to come up with ways of making things better, more efficient, safer and more user-friendly – and this is what we mean by innovative leadership.

#### Hygiene monitoring Ultimate perfection

Our products enable companies in the pharmaceutical, cosmetic and food industries to substantiate that their production processes respond to the most demanding purity and hygiene standards. The challenges confronting our customers are also our challenges and so naturally, Biotest HYCON and heipha Dr. Müller products are also manufactured in certified cleanrooms. This ensures that the hygiene monitoring products destined to assure the purity of our customers' products do not themselves contaminate the production process.

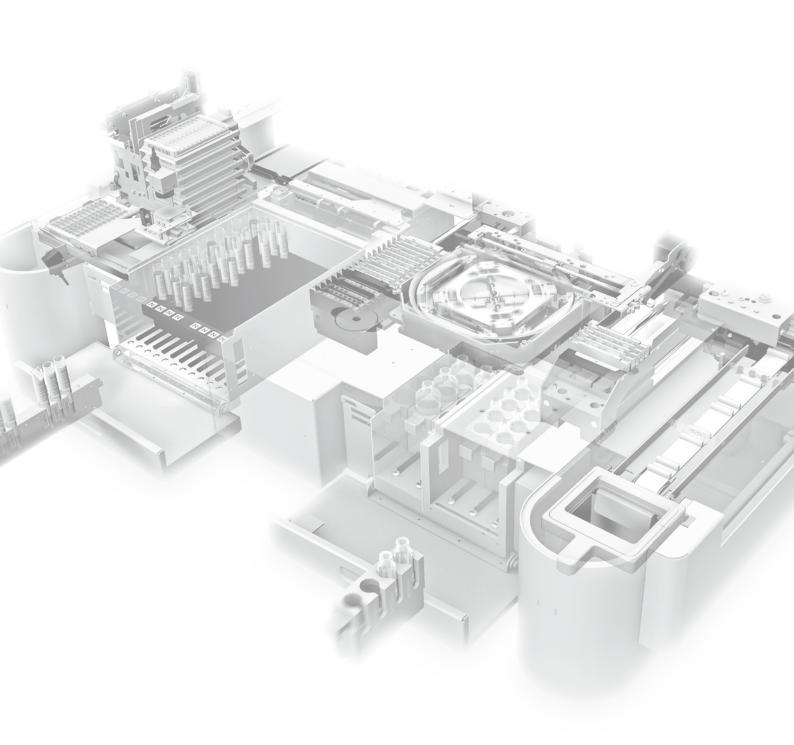


Innovative products, modern facilities: Biotest HYCON and heipha Dr. Müller.

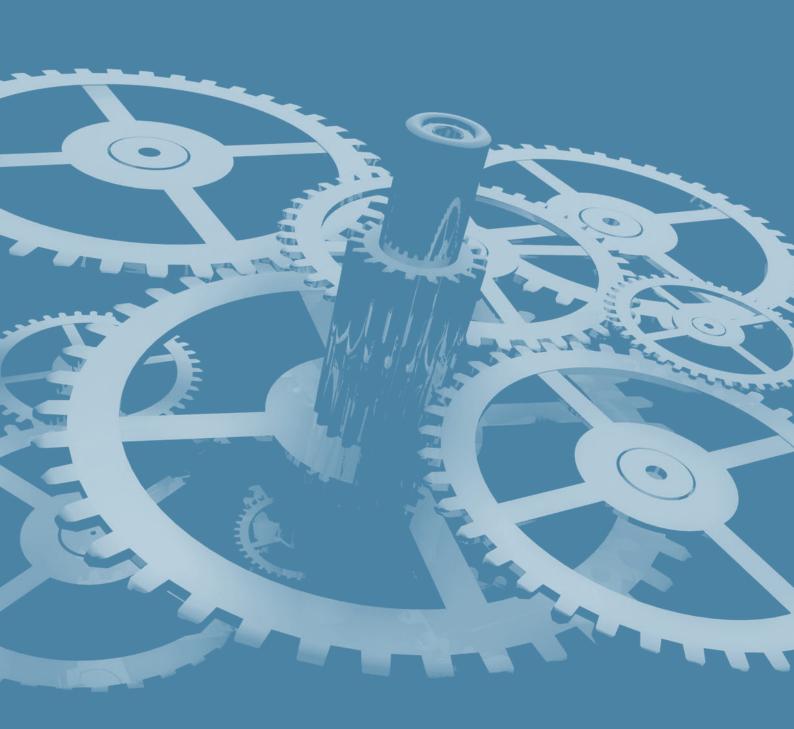


#### The Biotest solution for the paperless laboratory

By integrating heipha and HYCON products into a single piece of client software for planning, data processing and software analysis purposes, Biotest is now taking the next step towards the paperless laboratory. The system is compatible with the established laboratory data processing systems and facilitates efficient and safe hygiene monitoring diagnostics.



## WHY SHOULD BLOOD BANKS AND TRANSPLANTATION CENTRES BUY QUALITY PRODUCTS?



# BECAUSE THAT WAY, THEY CAN ACHIEVE A DOUBLE SAVING: IN ERRORS AND COSTS.

In diagnostics for transfusions and transplantations, reliable quality is of prime importance. Since the treatment is based on the diagnosis, savings in this area can sometimes carry a very high price. Far better to rely on the competence and quality offered by a premium supplier – and, ultimately, to save money by doing so.

## **QUALITY BORN OUT OF TRADITION**

Biotest is among the pioneers in haematological diagnostics. For more than 60 years, we have been committed to simplifying the most demanding and complex diagnostic procedures with the aim of ensuring that they can be safely and efficiently used as a matter of routine.

The pressure on the health services to reduce costs is enormous. In order to guarantee the best possible medical state-of-the-art treatments for everyone in the longer term, it is necessary to use every available efficiency resource.

One way is by automating the routine processes, for example in blood group diagnostics. In TANGO<sup>®</sup> optimo, Biotest has developed a solution which is tailored to suit the needs of smaller and medium-sized hospitals and haematology laboratories.

Typical of these is a hugely fluctuating workload. Peak times with large numbers of samples arriving late mornings or afternoons contrast with quieter periods. Neither the peaks nor the quiet times present a problem for TANGO<sup>®</sup> optimo. While peak workloads can be easily packaged and scheduled, the machine will quickly return to standby after the quiet periods, partly because the reagents can be stored cold.

The TANGO<sup>®</sup> multilink software launched last year will offer laboratories further opportunities of increasing the efficiency of their processes. The first of its type, this software allows for location-independent validation of blood sample analyses. Using a browser-based platform with password-protected login, users can access the data they need from any PC. This makes it possible for associated laboratories to log their validation results in one location and it also enables physicians on call, but not attending patients, to act as consultant specialists for laboratories with whom they work. Beyond this, it enhances the quality of the service, since in the event of any doubt, or in the case of particularly difficult issues, a second opinion can be sought quickly and without further effort (see box).

Biotest has 60 years of experience in setting new benchmarks in quality. In 1948, just two years after its establishment, the company was already among the pioneers of rhesus-factor test serums. Since then, we have been pursuing our aim of transforming complex diagnostic processes into simple, safe and proven test systems for routine use.

Another particular core focus of the company, along with ensuring state-of-the-art technology and top quality reagents, relates to operator training. Only welltrained staff can achieve the highest standards of quality and safety in the laboratory: our contribution to this is the comprehensive training programme we offer, whose lectures and courses cover the complete range of immunohaematology, and also include transplantation and infection diagnostics.



Biotest is continually improving the system for automatic blood group typing, TANGO® optimo.

## Working with TANGO<sup>®</sup> multilink: One user reports on her experiences



In our organisation, a brief introduction to the structure and main functions of the software was enough for us to start working with TANGO<sup>®</sup> multilink. User specifications and requirements were implemented by the software developer at short notice.

All the information relating to an examination, such as patient data, test materials, batch documentation and user data, can be called up in just a few steps. Any changes the user makes to the analysis results proposed by the system, including any comments, are documented as such and are therefore easily identifiable. The analysis data released by the system with all related information is available to physicians for validation of their diagnosis. This is an important basis for assessing response findings,

#### **Inke Hellmann**

Physician, Deputy Head of Quality Control DRK Blutspendedienst Nord gemeinnützige GmbH (German Red Cross Blood Donation Centre North) especially when the place where the examination is carried out differs from the place where the diagnosis is made.

In the assessment of complex cases within immunohaematology, comparison with preliminary examinations and the associated response findings is often helpful. The software facilitates such comparison at the level of individual response findings as well as the final diagnosis report. One click displays earlier diagnosis results and provides an interpretation of response over time. In terms of managing the findings, the search function of the software makes it possible to quickly find diagnosis results, using various search parameters.

# **Biotest**

## Biotest's products have one thing in common: there is an urgent need for them, and many are even considered indispensable. Their high ethical value is the basis for the sustainability of the company's economic value.

We are concentrating on our strengths and aim to achieve income-oriented growth in each of our segments.

In a number of markets, Biotest is already the leading manufacturer or one of the major suppliers. We are working on further consolidating this position and expanding it – in the interests of patients, users, our partners and our employees.

And last but not least, for the benefit of our shareholders.



Prof. Dr. Gregor Schulz, Chairman of the Management Board, and Dr. Michael Ramroth, Chief Financial Officer of Biotest AG.

"QUALITY PRODUCTS, THE POWER OF INNOVATION, RELIABILITY IN RELATIONSHIPS WITH PARTNERS AND EMPLOYEES – THESE ARE THE DISTINCTIVE HALLMARKS OF BIOTEST."

## Dear Shareholders,

The crisis in the financial markets and its impact have greatly heightened the importance of value as an issue in the public debate. This applies both to the economic as well as – and perhaps even more – to the ethical dimension. What is the value of a product, an asset or service offered to customers, associates, employees and society? Is the price/value ratio appropriate?

On the preceding pages, we gave four examples of the value of Biotest's business and products. The high ethical relevance of our business shapes the company and its actions. Our Plasma Proteins save lives and alleviate the suffering of the chronically ill. Our medical diagnostic products constitute the basis for treatments which are both safe and appropriate. Our microbiological monitoring guarantees the highest levels of purity, for example, in the production of drugs, while the primary focus of our Biotherapeutics segment is the development of new treatments for the most serious, frequently incurable diseases.

Quality products, the power of innovation in research and development, reliability in relationships with partners and employees – these are the distinctive hallmarks of Biotest, and the foundation of the company's success.

In financial terms, 2008 has proved to be another record year for us. Sales climbed to EUR 423.0 million, which was markedly above target, and the same applies to the operating profit, which, at EUR 55.6 million, was as high as never before in the history of Biotest. Even adjusted for the effects of acquisitions, the results show significant and profitable growth.

However, the financial indicators reflect only some of the factors which helped to make 2008 another very good year for Biotest. In many respects, we have strengthened our position as global specialists for innovative immunology and haematology.

Most striking is our expanded commitment in the USA. The integration of Biotest Pharmaceuticals Corp. (BPC) was completed within a few months and ran smoothly. Our expectations of the new US company in terms of sales and income potential have been exceeded and our sincere thanks and recognition of all their efforts are due to the entire BPC team under the leadership of Dr. Rainer Pabst and Jordan Siegel and to all those involved in the integration process. Work has begun on the expansion of our Plasma Proteins production plant in Boca Raton, which will create the conditions for further growth in the attractive US market. The US growth market is also the core focus for the further development of our business with diagnostic products. In fact, the former strategic business units of Microbiology and Immunology are now independent segments operating as Microbiological Monitoring and Medical Diagnostics.

Since FDA approval was obtained for 39 manual reagents, we are able to operate in the USA as a full service provider of automated and manual blood group diagnostics. Following the market approval granted at the end of 2007, in the past year we have been successful in establishing a customer base for our microbiological monitoring products.

However, Biotest has also accomplished a great deal outside the USA. The start-up of a second chromatographic processing plant has enabled us to double our immunoglobins production capacity from two to four tonnes per year. At the same time, we have expanded the capacity of our plasmapheresis centres and our fractionation facilities, the latter by agreement with the Dutch-Belgian company C.A.F.-D.C.F., with which we have already enjoyed a trusting working relationship for decades. The agreement, under which Biotest will be able to use our partner's facility in Brussels to fractionate up to 300,000 litres of blood plasma per annum, puts the relationship onto a new footing.

For the Microbiological Monitoring segment, 2008 has been synonymous with sustained growth. By investing in the Eppelheim site infrastructure and a series of product innovations, we have created the basis for the continued success of Biotest HYCON and heipha Dr. Müller GmbH.

As anticipated, the outsourcing of transfusion, transplantation and infection diagnostic operations to an independent company has opened up new perspectives for the Medical Diagnostics segment. Although income for 2008 remained negative, there are distinct signs of an upward trend. As before, the search for the right strategic partner for this business division has high priority.

The development of monoclonal antibodies (mAb) made considerable progress in 2008. Two of the three agents are now in clinical development and already, the interim results of a Phase IIa trial with mAb BT-061 in the treatment of psoriasis are showing marked and sustained clinical improvements at very low dosages. Based on these promising results, at the end of 2008, we approached a number of international pharmaceutical companies, which we believe might make suitable partners for the global development and marketing of BT-061. In a Phase I trial, when administered to patients suffering from multiple myeloma, mAb BT-062 proved to be generally well tolerated at primary dosage stages.

The successes achieved by Biotest in its operating business and the strategic advancement of the company have been rewarded by the capital market. Up until autumn 2008, the share price of ordinary and preference Biotest shares had been enjoying a stable upward trend, which led to new record price levels. However, even Biotest shares are not immune to the collapse of the global stock markets as a consequence of the banking crisis. Notwithstanding the situation, the price of ordinary and preference shares closed the year higher than at year-end 2007, while in the same period, the SDAX had lost approximately half its value.

Even more marked is how Biotest's market capitalisation value is rated by the stock markets. Last year, it rose by 39.2 %, while in the last five years, the value of the group has more than increased tenfold.

Biotest is well equipped to confront the challenges of the future: success in the operating business, very promising development projects with considerable potential, a sound financial basis secured by long-term agreements, good partners and associates and, above all, dedicated, competent and capable staff.

Given the urgent necessity for our products and the fact that in many cases, there are no substitutes, in principle, Biotest is less susceptible to economic fluctuations. However, it would be unrealistic to maintain that we are entirely immune to developments in the global economy. Our announcements regarding sales and profit targets are therefore subject to higher risks compared to precedent forecasts. We are expecting a growth in sales of about 10 % for the years 2009 and 2010 each. We are intending to maintain the operating profit on the same level as in 2008.

All the experts share the conviction that companies with a sound basis and a sustainable, future-oriented business model will not only survive the current crisis, but will emerge even stronger. Biotest has proven that it is just such a company.

We are convinced that this situation will not change in the future and invite you to accompany us on our journey.

Sincerely yours,

Professor Dr. Gregor Schulz Chairman of the Management Board

Mr. Kannoth

Dr. Michael Ramroth Chief Financial Officer

## Highlights of the financial year



#### January 2008

Biotest transfers the development, production and marketing of medical diagnostic systems and products to Biotest Medical Diagnostics GmbH, an independent company. This facilitates more efficient cost allocation and increases flexibility in the search for strategic partners.

#### **March 2008**

The US approval authority, the FDA, grants orphan drug designation to the BT-062 monoclonal antibody in the indication of multiple myeloma. The corresponding decision from the European Union authorities follows in December 2008. Biotest Medical Diagnostics GmbH moves into its new production, research and office building in Dreieich.

#### April 2008

The procedure for approval of the Hepatect® immunoglobulin and the Haemoctin® coagulation preparation in additional European countries is successfully completed. Hepatect® may now also be sold in the UK, for example, where the immunoglobulin is approved for intravenous administration in the prevention of hepatitis B.

#### May 2008

Biotest and the Johannes Gutenberg University in Mainz sign a cooperation agreement for pre-clinical research of the BT-061 monoclonal antibody in further indications.

In view of dynamic business growth, the production of Plasma Proteins switches to non-stop triple-shift operations. From now onwards, the fractionation facility produces around the clock seven days a week.

The Annual Shareholders' Meeting of Biotest AG approves the Board of Management's proposal to pay a significantly higher dividend to shareholders than in the previous year. This marks the fifth consecutive increase in distribution at Biotest.

#### June 2008

Biotest opens a new technology centre in Eppelheim, very close to the location of heipha Dr. Müller GmbH, where the Biotest HYCON product range will be developed, manufactured and marketed.

#### **July 2008**

The BT-061 monoclonal antibody is approved in the USA as innovative development and granted comprehensive patent protection.



# August 2008

Biotest signs a cooperation agreement with diagnostic company Abbott for the planned clinical Phase III trial for approval of Cytotect<sup>®</sup> in the indication of congenital cytomegalovirus infection.

The first blind analysis as part of a clinical Phase I/IIa trial in the indication of psoriasis provides a clear indication of the efficacy of BT-061. The analysis also confirms assessments regarding safety and tolerability.

The FDA grants Biotest Medical Diagnostics GmbH approval to market 39 products for manual blood group typing in the USA. Biotest can now act as a full service provider in the world's biggest and most attractive market.

The clinical development of BT-062 in the indication of multiple myeloma is launched. The antibody displays good levels of tolerability in the initially low dosages administered.

#### September 2008

In Dreieich, work to set up the second chromatographic purification plant for immunoglobulins is completed. However, extensive validation work and consistency batches are required before acceptance of the plant by the authorities. From 2009 onwards, Biotest will be in a position to produce four instead of two tonnes of immunoglobulins per year.

# October 2008

The facility to produce monoclonal antibodies at Biotest Pharmaceuticals Corporation in Boca Raton/USA starts pilot operations following completion of the conversion. There is the option of installing a second fermentation plant to double capacity.

# November 2008

Following approval of the Haemonine® factor IX preparation to treat type B haemophilia, Biotest complements its range of coagulation factor products.

# December 2008

Through an agreement with its long-time business partner C.A.F.-D.C.F. increases the annual fractionation facilities to 300,000 litres.

# The Share

# Increase in share value achieved

In an environment that was defined by the crisis affecting the financial markets and increasingly the economy as a whole, Biotest shares considerably outperformed the market. While share prices tumbled across the board, both share classes closed significantly higher than in the previous year.

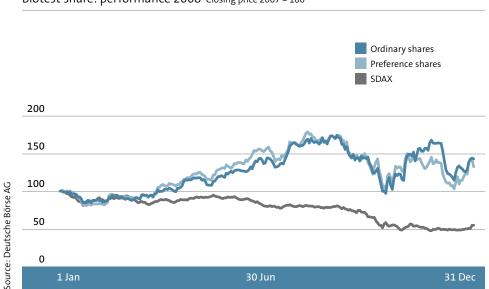
# Overview of stock market activities in the reporting year

In 2008, the stock markets were characterised by the international crisis in the financial markets and its consequences. The selection indices of the Frankfurt stock exchange, DAX, MDAX and SDAX, recorded considerable losses in the first six months of the year. Share prices fell globally across the board in September and October, in the wake of the collapse of the US investment bank Lehman Brothers and the associated concern that the entire global financial system might crash.

In the aftermath, the increasingly apparent negative effects of the financial market crisis on the real economy weighed heavily on share performance. High volatility reflected the uncertainty of many market players.

The DAX closed 2008 at 4,810.20 points compared with 8,067.32 points at the end of the previous year, representing a decrease of 40.4%. The SDAX was down by 46.1%, closing the year at 2,800.73 points compared with 5,191.56 points at the end of 2007.

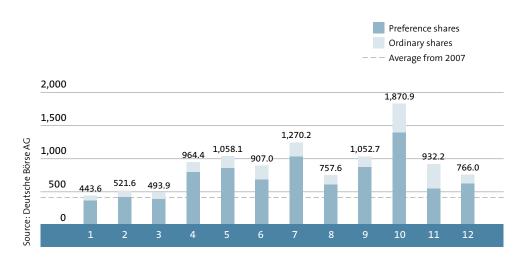
The sector index "Prime Pharma and Health Care Performance" of Deutsche Börse decreased by 23.1% to 1,429.64 points.



Biotest share: performance 2008 Closing price 2007 = 100

# **Performance of Biotest shares**

During the past year on the stock market, both classes of Biotest AG shares considerably outperformed the market as a whole. On 30 December 2008, ordinary shares closed at  $\leq$ 54.56 compared with a closing price of  $\leq$ 38.00 the previous year, which represents an increase of 43.6%. The 2008 year-end closing price for preference shares was  $\leq$ 45.77, which corresponds to a rise of 33.1% on year-end 2007 ( $\leq$ 34.40).



Volume of securities traded Monthly values from the order book statistics (in thousand securities)

Share prices were on a stable upward trend, until they too were caught up in the downhill slide resulting from the financial market crisis. In the meantime, ordinary and preference shares reached record peaks of  $\in$ 67.00 and  $\in$ 64.00 respectively. Both share classes reached their annual lows of  $\in$ 30.00 (ordinary) and  $\in$ 25.41 (preference) at the beginning of the year.

The total shareholder's return for 2008 amounts to 44.4% per ordinary share and 34.1% per preference share. The total shareholder's return consists of the amount by which the value of shares has increased plus the dividend paid out for the financial year concerned.

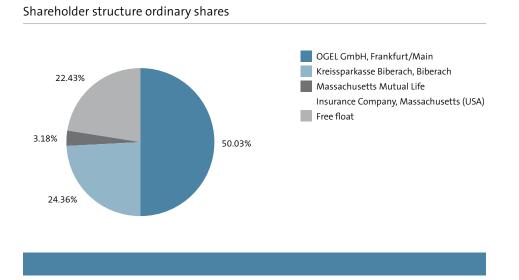
For 2008, the Board of Management of Biotest AG is proposing to distribute a dividend of  $\leq 0.30$  per ordinary share and  $\leq 0.36$  per preference share to shareholders. This proposal is to be approved by the Annual Shareholders' Meeting on 7 May 2009.

The positive development in the share price resulted in a further increase in the stock market value of Biotest AG compared with the previous year. On 30 December 2008, Biotest AG was valued at  $\in$ 594.8 million on the stock market, which represents a 39.2% increase on the market capitalisation at the end of 2007 ( $\notin$ 427.2 million).

Of this, €235.0 million was attributable to preference shares listed on the SDAX, compared with €176.6 million at the end of 2007. Biotest was ranked No. 102 in terms of free-float market capitalisation, which is a significant factor in the composition of the selection indices of Deutsche Börse.

# Shareholder structure

At the end of 2008, Biotest AG's share capital amounted to around €30 million, divided into 6,595,242 ordinary shares and 5,133,333 preference shares without voting rights. According to information which is publishable under the terms of Section 21 WpHG (German Securities Trading Act), the shareholder structure for ordinary shares was as follows:



OGEL GmbH has announced that it is controlled by Dr Cathrin Schleussner, a member of the Supervisory Board of Biotest AG. The Biotest AG shares held by the members of the Schleussner family have been consolidated in OGEL GmbH.

#### Communicating with investors and the public

In financial year 2008, Biotest maintained an ongoing close dialogue with shareholders, analysts, the media and the public. The Group's sales figures and results for 2007 were presented on 20 March 2008 at a press and analysts' conference in Frankfurt/ Main, where they were explained in detail. On 6 November 2008, also in Frankfurt/ Main, the Board of Management presented the business and income development and reported the progress of implementation of the corporate strategy in the first nine months of the financial year. Publication of the interim reports for the first quarter and the first six months of 2008 was accompanied by the relevant press releases.

The interim reports following the first three, six and nine months were published within the 45-day deadline after the relevant reporting dates stipulated by the German Corporate Governance Code (DGCK).

The Group income statement and balance sheet for financial year 2007 were published on 20 March 2008, and the complete consolidated annual financial statements and 2007 Annual Report were made available on 28 March 2008. This also fulfilled the DGCK requirement (a maximum of 90 days after the reporting date). We published preliminary sales and income figures for the financial year and information on the key events of financial year 2007 on 22 February 2008.

#### Data and key figures for Biotest shares

€	2008	2007	2006
Dividend per ordinary share <sup>1)</sup>	0.30	0.30	0.24
Dividend per preference share <sup>1)</sup>	0.36	0.36	0.30
Earnings per share	2.17	1.39	1.48
Additional dividend rights preference shares	0.06	0.06	0.06
Earnings per preference share	2.23	1.45	1.54
Cash flow <sup>2)</sup> per share	6.95	5.06	4.40
Ordinary shares			
Opening price XETRA	34.40	29.74	24.65
High XETRA	67.00	42.25	39.40
Low XETRA	30.00	31.38	24.00
Closing price XETRA	54.56	38.00	29.96
Preference shares			
Opening price XETRA	38.00	22.30	22.45
High XETRA	64.00	39.09	30.10
Low XETRA	25.41	22.50	19.61
Closing price XETRA	45.77	34.40	22.17
Market capitalisation at year-end (€ million)			
as of 30 December (€ million)	594.79	427.21	283.09
thereof: ordinary shares	359.84	250.62	179.63
thereof: preference shares	234.95	176.59	103.46

<sup>1)</sup> Value for 2008: proposal

 $^{\scriptscriptstyle 2)}$  Operative cash flow before changes in working capital

The Board of Management explained the corporate strategy and operational development of the company in a number of presentations and individual discussions taking place at conferences, industry forums and roadshows. We also made ourselves available throughout the year to answer queries from shareholders, analysts and journalists.

We advised the public of events significant to the company's development and valuation without delay in the form of in ad hoc notifications and press releases. We have considerably stepped up our press relations compared to previous years.

The Investor Relations pages of the Biotest Group website (www.biotest.de) contain all reports and publications released by the company as well as supplementary information.

Biotest published the complete consolidated annual financial statements for 2008 together with the Group Annual Report on 23 March 2009. We reviewed our business and income development at Group level in greater detail at a press and analysts' conference held on 11 March 2009 in Frankfurt/Main.

# Group management report

# The financial year in review

In financial year 2008, Biotest achieved new record figures in the company's history for sales and income. The business volume rose by 29.6% to €423.0 million, with operating profit up by as much as 44.4% to €55.6 million. Even excluding the contribution of the US Plasma Proteins business, acquired at the end of the previous year, the company recorded significant growth.

We successfully concluded the integration of the Biotest Pharmaceuticals Corporation into the Group within a few months. In all segments, considerable progress was made with regard to the internationalisation of our business as well research and development.

The Biotest Group's capital structure is sound, and sufficient availability of financial resources is guaranteed at present as well as in the medium and long term.

Biotest has strengthened its position as a global specialist for innovative immunology and created the conditions for further profitable growth.

In 2008, the financial market and economic crisis had no measurable negative impact on operating business. There is a possibility of dampening effects for the current year, but the extent of these should be limited.

# About Biotest – business and framework conditions

# Group

Biotest is a pharmaceutical, biotherapeutical and diagnostic group active in research and production, specialising in haematological, immunological and microbiological applications.

The company develops, produces and markets the following products:

Immunoglobulins, coagulation factors and albumins. Biotest is one of the six largest global companies which process blood plasma.

Medical diagnostic products, such as reagents and systems which for example find their application in blood transfusions.

Microbiological tests for hygiene monitoring in the pharmaceutical and food industries as well as in hospitals. In all segments, considerable progress was made.

A fourth area of the company's operations is the development of monoclonal antibodies, among others for the indications rheumatoid arthritis, psoriasis, multiple myeloma and systemic lupus erythematosus.

### Segments

With effect from 1 January 2008, Biotest adjusted its reporting system. The figures for the previous year were adjusted accordingly.

The company now reports on business developments according to the four operating segments Plasma Proteins, Microbiological Monitoring, Medical Diagnostics and Biotherapeutics, with the Biotherapeutic segment currently focusing exclusively on research and development.

The overall Group management costs as well as non-attributable costs are included in the fifth segment, Corporate.

Autonomy of Medical Diagnostics is a prerequisite for strategic partnership. The Microbiological Monitoring and Medical Diagnostic segments evolved from the former Diagnostic segment. The two segments are subject to separate management at global level with their own sales structures and production and research divisions. In the search for a strategic partnership for Medical Diagnostics, a prerequisite is worldwide autonomy.

#### **Corporate structure**

Biotest AG is the Group's parent company. It is a joint stock company under German law (Aktiengesellschaft) with its registered office in Dreieich near Frankfurt/Main. Vital parts of the business are processed within this company. In addition, it has investments in subsidiaries based in 11 countries. The most important subsidiaries are listed below. The companies not included in this description are essentially pure marketing units.

**Biotest Pharma GmbH:** This company owns the Plasma Proteins production units in Dreieich and the product licences for the goods manufactured there. Biotest Pharma GmbH makes all licences and facilities available to Biotest AG as part of a licence agreement and lease agreement respectively. Research and development is carried out by Biotest AG as a service provided to Biotest Pharma GmbH.

**Plasmaservice Europe GmbH**, Dreieich, **Plasmadienst Tirol GmbH**, Innsbruck, and **Plazmaszolgálat Kft.**, Budapest: Subsidiaries in which the operations of the European plasma collection centres are pooled.

**Biotest Pharmaceuticals Corp.,** Boca Raton (BCP): The company encompasses the Plasma Proteins activities in the USA including the operations relating to the plasma collection centres based in the USA. The company has sole responsibility for production and distribution.

**Biotest Medical Diagnostics GmbH,** Dreieich: The company develops, produces and markets goods for immunological diagnostics.

**Biotest Diagnostics Corp.,** Rockaway: The company distributes products for immunological and microbiological diagnostics in the USA.

**heipha Dr. Müller GmbH,** Eppelheim: The company develops, produces and markets systems to monitor cleanroom and surface conditions, as well as raw materials and end products.

With the exception of heipha Dr. Müller GmbH, all the companies mentioned are wholly-owned by the Biotest Group. Biotest AG has a 51% stake in heipha Dr. Müller GmbH, which is fully consolidated in the Microbiological Monitoring segment.

As of the reporting date, 60.5% of employees of the Biotest Group were based in Germany and 30.9% worked in the USA.

# Shareholder structure

Biotest shares (ordinary and preference shares) are listed on the official market (Prime Standard) of the Deutsche Börse, with the preference shares listed in the SDAX selection index. The shares are also traded on other regional stock exchanges. With a 50.03% stake of the capital attributable to ordinary shares, OGEL GmbH, with its registered office in Frankfurt/Main, is the majority shareholder in Biotest AG. The members of the Dr. Schleussner family have pooled their Biotest shares in this company.

Kreissparkasse Biberach holds 24.36% of the company's ordinary shares and according to its notification dated 5 December 2008, Massachusetts Mutual Life Insurance Company held 3.18% of ordinary shares.

#### **Plasma Proteins segment**

# Products

Biotest obtains proteins from human blood plasma, which can be broken down into three groups: immunoglobulins, coagulation factors and albumins. They are used in the treatment of congenital and other diseases and are applied in the medical fields of haematology and clinical immunology. Another area of application is accident and emergency medicine.

# Immunoglobulins

Immunoglobulins are generated by the immune system as specific antibodies to combat antigens. Biotest produces and markets the following immunoglobulins:

- Intraglobin<sup>®</sup>/Intratect<sup>®</sup>: polyvalent immunoglobulins used in substitution therapy to treat antibody deficiency, primary humoral immunodeficiencies or secondary antibody deficiency syndromes, caused for example by chronic lymphatic leukaemia. Further indications are the treatment of children with HIV infections and autoimmune diseases.
- Pentaglobin<sup>®</sup>: IgM-enriched immunoglobulin used to treat severe bacterial infections.
- Varitect<sup>®</sup>: specific immunoglobulin used in the prophylactic and general treatment of herpes zoster virus infections (shingles), to treat immune system deficiencies (e.g. leukaemia) and neonatal and premature babies.
- Cytotect<sup>®</sup>/Megalotect<sup>®</sup>: specific immunoglobulin used in the prevention of cytomegaloviral infections.
- Hepatect<sup>®</sup> and Nabi HB<sup>®</sup>: specific immunoglobulins mainly used to prevent hepatitis B. Hepatect<sup>®</sup> is approved in Europe and Nabi HB<sup>®</sup> in the USA.

#### **Coagulation factors**

Coagulation factors used to treat haemophilia are employed both prophylactically and to stop acute bleeding. Biotest produces the following preparations:

- Haemoctin®: coagulation factor VIII for the treatment of type A haemophilia
- Haemonine<sup>®</sup>: coagulation factor IX for the treatment of type B haemophilia. Until approval of Haemonine<sup>®</sup> in autumn 2008, Biotest sold the Faktor IX XDN Biotest product under licence

#### Albumins

Albumin is used to restore the volume balance in the event of a loss of Plasma Proteins, for example as a result of surgery or burns. Biotest produces and markets Human Albumin Biotest<sup>®</sup> and Biseko<sup>®</sup>, a Plasma Proteins solution.

#### Processes

The raw material used in the production of Plasma Proteins is human blood plasma, which is collected from voluntary donors. The plasma is either obtained from conventional blood donations or by means of plasmapheresis, where only the plasma is taken from the blood and the remaining cellular elements (e.g. red blood cells) are reinfused directly to the donor. This procedure facilitates the collection of up to two plasma donations per week, whereas a minimum of two months must pass between two blood donations. In Germany, donors may provide a maximum of 38 plasma donations per year, while the number is slightly higher in the USA. Biotest exclusively uses plasma from qualified donors, i.e. donors who give blood or plasma regularly and are subject to stringent health checks.

Biotest exclusively uses plasma from donors who are subject to stringent health checks. In plasma fractionation, specific proteins are extracted from the raw material after a mandatory storage period of 60 days and exhaustive prior testing. This is carried out after ethanol precipitation by means of a centrifuge or special filters (filter aid procedure). In its Dreieich location, Biotest's production is based on the filter aid procedure. BCP uses the centrifugation method.

After fractionation, the substance is subjected to precision purification processes, including chromatography. The individual production stages incorporate several viral depletion and/or deactivation processes, including nanofiltration. The complete production process is subject to the most stringent standards of safety and purity.

Biotest covers the entire value added chain in the Plasma Proteins segment. The company's own plasmapheresis centres in Europe and the USA supply around 40% of the plasma processed. Biotest obtains the remaining volume from suppliers under the terms of long-term agreements. At the Dreieich location, we have fractionation capacities of some 700,000 litres per year. In addition, Biotest has concluded an agreement with Belgian company C.A.F.-D.C.F., under which the company has access to an annual fractionation volume of approximately 300,000 litres. The C.A.F.-D.C.F. facilities in Brussels are included in the approval dossiers for Biotest's Plasma Proteins, so that any plasma fractionated there can be processed in Dreieich to produce coagulation factors, immunoglobulins and albumin.

Plasma Proteins are sold directly by Biotest Group companies or its partner companies. All sales activities are initiated and coordinated by Biotest. Research, development and the necessary activities involved in the process to obtain drug approval are the responsibility of specialist departments.

In addition to marketing medical products under its own brand names, Biotest also manufactures Plasma Proteins for other companies and national institutions through toll manufacturing agreements. Here, partners supply plasma or preliminary products to Dreieich and receive the medical preparations obtained from processing in return.

The activities required on the part of Biotest as part of the process for developing and approving Plasma Proteins are managed by the Medical/Regulatory Affairs service department. As the Group's centre of competence, employees in this department also process the relevant tasks on behalf of the Biotherapeutic segment.

# **Key locations**

The Plasma Proteins processing facilities are located in Dreieich and Boca Raton. Of the company's own plasmapheresis centres, which currently number 21, ten are based in Europe (mostly in Germany) and 11 in the USA.

The complete production is subject to the most stringent standards of safety and purity.

All sales activities worldwide are initiated and coordinated by Biotest.

#### **Key markets**

The relevant markets for Biotest's business comprise the sales markets for immunoglobulins, coagulation factors and albumin, as well as the supply and demand for fractionation capacity (toll manufacturing). Biotest markets Plasma Proteins worldwide. The core markets are Europe and the USA where products are generally distributed to individual buyers or buyer networks. Business with developing countries and emerging markets is mainly based on tenders for the supply of high volumes, for example the total requirement of a six-month period.

The USA is the biggest market for immunoglobulins worldwide. With annual demand amounting to approximately 35 tonnes, it comprises around one third of the global market share, while approximately 25% is attributable to European Union countries.

In most cases, treatment with impac Plasma Proteins is life-critical ever, a to patients. health

As a rule, treatment with Plasma Proteins is life-critical to patients. In this respect, the impact of overall economic developments on the market situation is limited. However, an indirect correlation results from the fact that the budgets of state-financed health systems are affected by the national economies.

In principle, a public health system tends to improve in tandem with increasing affluence, although there may be a degree of time delay before the effects become evident. In particular, in the treatment of haemophiliac patients, this can generate growth potential. According to a survey carried out by the World Federation of Hemophilia (WFH), only around 25% of all haemophiliacs worldwide are receiving appropriate treatment.

With regard to immunoglobulins and albumin, there is no alternative to plasmabased products. In the treatment of haemophilia, however, biotechnologically produced (recombinant) factors are also used. This applies particularly in the USA and UK. In other European countries, approximately 40% of products employed are plasmatic and around 60% recombinant.

Price developments in the global blood plasma market have a considerable impact on the cost of goods sold at Biotest. Furthermore, the prices achievable for finished products largely depend on the total amount of Plasma Proteins available in the global market in relation to demand. The most important indicator in terms of the development of supply volume is the number of plasmapheresis centres established and their respective capacity.

Biotest is in the group of the six largest suppliers of the global Plasma Proteins market. With a share of the global Plasma Proteins market totalling 4%, Biotest is in the group of the six largest suppliers. Within Biotest AG's European core markets, our aggregated market share amounts to an estimated 14%. In some countries the share is considerably higher.

In Western Europe, Biotest's share of the immunoglobulin market amounts to 15%, while the company covers more than 20% of demand in Germany.

With regard to coagulation factors, we have a 12% market share worldwide and a 22% share within Europe.

With Nabi HB<sup>®</sup>, Biotest Pharmaceuticals Corp. covers over 50% of the market for products to prevent infection with hepatitis B following liver transplantation.

#### **Regulatory environment**

In Germany, the authority for the approval of Plasma Proteins is the Paul Ehrlich Institute (PEI), and the production facilities of Biotest are subject to mandatory approval from the regional board based in Darmstadt and the US Food and Drug Administration (FDA).

In the EU member states, Plasma Proteins are approved either according to the centralised procedure governed by the European authority, EMEA, and the European Commission, or in line with the mutual recognition procedure/decentralised procedure.

In the USA, drugs are subject to the regulatory provisions of the Food and Drug Administration (FDA). Along with other prescriptive laws and regulations, the US Food, Drug and Cosmetics Act (FDCA) regulates the entire manufacturing process for pharmaceutical products from research to marketing.

Biotest is a member of the Plasma Proteins Therapeutics Association (PPTA) and has adopted the association's safety standards for obtaining and processing blood plasma. These standards go beyond the legal requirements. Compliance with the standards is documented by the Q-SEAL quality seal, which is awarded upon completion of a comprehensive certification process. On 31 December 2008, apart from Biotest, only four other companies were authorised to use the Q-SEAL mark.

For pre-clinical and clinical research as well as the manufacturing and approval processes, Biotest procedure follows the guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This also applies to activities in the Biotherapeutic segment. Biotest is one of five companies who are authorised to use the Q-SEAL mark.

# **Microbiological Monitoring segment**

This segment pools the activities of Biotest AG (Biotest HYCON product division) and heipha Dr. Müller GmbH.

# Products

Biotest develops, produces and markets reagents, devices and systems used in hygiene monitoring for air, surface and manufacturing processes, as well as procedures to test end products for potential microorganism contamination.

The programme includes air samplers, particle counters and a wide range of solid (contact media and sedimentation plates) and liquid culture media (in bags, bottles and containers) as well as special media for microbe identification. Air samplers, particle counters and agar strips originate from the Biotest HYCON product division and the remaining products are manufactured by heipha Dr. Müller GmbH. All products are CE certified.

We progressively develop the various products further to achieve automated documentation of hygiene monitoring, making this process safer and more efficient.

#### Processes

The raw materials used in the production of test media vary and include agar, peptones and salt as well as ready-made blends. Following the goods-in check, the materials released are put together and weighed according to the relevant formulation for each medium.

The raw materials are poured into so-called batch tanks according to the manufacturing protocol and dissolved completely by adding purified water, mixing and heating. We control and monitor this process on the basis of various defined parameters.

The medium is then sterilised and filled in an automated filling process onto plates and strips and into test tubes, bottles and bags. The entire process is subject to stringent safety and quality controls based on random samples.

Prior to release of each batch for sale, the product goes through several quality tests. Depending on the product, packaging is automated. For example, ICR and ICR plus plates are wrapped three times in plastic film, labelled and then packed in cardboard boxes. Prior to release of each batch for sale, the finished product goes through several quality tests.

The manufacturing processes are in line with the Good Manufacturing Practice (GMP) guidelines and take place in controlled and appropriately certified cleanroom conditions. Individual pieces of equipment and system components are purchased from external suppliers.

Research and development is the responsibility of specialist teams. Cooperation agreements are in place with research institutes and other companies, for example in the field of system technology.

Microbiological products are marketed by Biotest AG and its subsidiaries as well as by partner companies. In most European countries, the USA and Japan, specialist sales teams support customers.

#### **Key locations**

The segment has production facilities at the headquarters of heipha Dr. Müller GmbH and at the microbiology technology centre in Eppelheim, as well as at the headquarters of the Biotest Group in Dreieich. Research and development relating to the Biotest HYCON and heipha Dr. Müller product lines is based in Eppelheim and that relating to any new technology in Dreieich.

#### Key markets

The global sales market for industrial microbiology products is estimated to be worth  $\leq 1,100$  million, with annual growth of between 4% and 6%, and includes a number of different industries. The largest segment is the food industry with around 50%, followed by the pharmaceutical industry. Another important area of application is cleanroom monitoring in hospitals.

The most important client group are companies from the pharmaceutical industry, which use the products to check for possible microbial contamination (bacterial and fungal) as part of stringent regulatory requirements. The cosmetic and food industries also increasingly buy our products.

In regional terms, Germany is the most important market with a share of approximately half of segment sales. heipha Dr. Müller GmbH is the leading supplier here for cleanroom monitoring solutions in the pharmaceutical industry. The second largest sales contribution comes from business with buyers in the USA, who account for around a fifth of annual sales.

Growth in the sales markets that are particularly relevant to Biotest is contingent on the economic sector development of the pharmaceutical industry. It is determined by factors such as the ever growing efforts made by the pharmaceutical industry to cut costs. heipha Dr. Müller GmbH is a leading supplier in Germany. Another important factor is represented by the escalating stringency of requirements on cleanroom monitoring stipulated by the authorities and the associated documentation in the pharmaceutical and food industries.

# **Regulatory environment**

heipha/HYCON products help buyers of these products to fulfil the high standards stipulated in the pharmacopeia (dispensatory) and required by the regulatory authorities with regard to hygiene monitoring, raw materials and end product controls.

The increasingly complex standards relating to manufacturing processes in the food industry result in more tests, for which our products are used.

In the USA, the FDA and the United States Department of Agriculture (USDA) are the competent approval authorities for our products. Prior to exporting culture media to the USA, one of the requirements is that producers must provide proof that the manufacturing process and end product are free from contamination by BSE pathogens.

Since January 2009, uniform regulations have applied in the European Union, Japan and the USA regarding the test media used for hygiene monitoring in the non-sterile areas within pharmaceutical production.

Increasingly complex standards result in more tests, for which our products are used.

# **Medical Diagnostics segment**

#### Products

In the Medical Diagnostics segment, Biotest develops products for use in automated and manual blood group typing. The core product is the TANGO<sup>®</sup> optimo system, which offers hospital haematology laboratories and blood banks fully-automated blood group typing. Biotest markets the equipment complete with the associated reagents and software.

The range of products also includes a comprehensive programme of test systems and reagents for tissue typing in transplantation and products for virological laboratory diagnostics.

#### Processes

The majority of products in the Medical Diagnostics segment are manufactured at the Biotest Dreieich location. The facilities and processes meet the quality standards of the European and US approval authorities. Biotest manufactures the products in specially equipped production rooms, which meet the requirements stipulated by the authorities.

The most important basic material for the majority of products used in blood group typing are monoclonal antibodies, which identify different blood group components. After additional processing steps, the raw material is filled into either bottles (for manual analysis) or microtiter plates (for use with the TANGO® system). The key product for the second area of immunohaematological diagnostics – antibody identification – are test cells, which are processed human red blood cells. Due to their limited shelf life, these must be produced every four weeks.

Similar to sales in the Microbiological Monitoring segment, products are sold directly by Biotest AG and its subsidiaries or by its partner companies.

### **Key locations**

Research and development activities as well as production and despatch of all products in the Medical Diagnostics segment are pooled at the headquarters of Biotest Medical Diagnostics GmbH in Dreieich.

#### Key markets

We estimate the global market volume for transfusion diagnostic products to be in excess of €500 million. Approximately 60% of this is attributable to hospitals, around 20% to blood banks and approximately 20% to medical laboratories. The US market is the largest of the regional markets, followed by the European countries.

The facilities and processes meet the quality standards of European and US authorities. We sell our products worldwide, with a focus on the markets in Europe and the USA. Major customers include hospital laboratories, blood banks and specialist laboratories.

Developments in the market environment are essentially determined by sector-specific factors, such as the number of transfusions and transplantations in the relevant countries. Another important factor is the ability of public health systems to reimburse costs.

While competition in Europe has been very fierce for years and is mainly dominated by pricing, the situation in the USA is fundamentally different. Alongside Biotest, only two other providers are currently authorised to sell their products in the market. The price level in the USA is significantly higher than that in Europe and other global regions.

# **Regulatory environment**

In the European Union, in-vitro diagnostics (IVD) must comply with the IVD Directive and the relevant national regulations derived from this Directive. CE certification is mandatory for all products and the prerequisite for this is a quality management system which complies with the provisions of the relevant international standards.

In the USA, diagnostic products may only be marketed with FDA approval. This approval is based on clinical trials in the USA, the results of which form part of the comprehensive approval documentation. In addition, regular audits are carried out by the US authorities as well as inspections prior to approval being granted.

Biotest is one of only three providers whose products are FDA-approved.

# **Biotherapeutics segment**

#### Products

In its Biotherapeutics segment, Biotest researches and develops the BT-061, BT-062 and BT-063 monoclonal antibodies (mAb). The lead indications are currently rheumatoid arthritis and psoriasis (BT-061), multiple myeloma (BT-062) and systemic lupus erythematosus (BT-063). With BT-061 and BT-062, two mAb are in clinical development and BT-063 is in the pre-clinical development stage.

#### Processes

Drug development is divided into different stages. In pre-clinical development, agents are tested in models or animal trials. Trials involving humans start with clinical Phase I. This stage focuses mainly on testing the tolerability and safety of the preparation. In Phase II and III trials, data is additionally collected on dosage and efficacy.

In the various development stages, Biotest works with partners from a variety of sectors. Cooperative agreements exist, in particular, for the investigation of new therapeutic principles and indications, the establishment of biotechnological production systems and manufacturing processes, the production of the required test material and in pre-clinical development.

All partner activities are controlled and monitored by Biotest AG.

#### **Key locations**

Employees in this segment are based in Dreieich and Boca Raton, USA.

# Key markets

According to estimates published by Nature Reviews/Drug Discovery magazine, in 2008 the global market for rheumatoid arthritis treatment reached a total volume of USD10.5 billion, of which more than 80% comprised biotechnologically produced agents.

Between 0.5% and 1% of the global population suffer from rheumatoid arthritis (RA). Anti-TNF treatments are currently finding the most widespread use. In simple terms, these suppress a part of the immune system and consequently inhibit the damage it causes to the body's own tissue (autoaggression) by neutralising inflammation mediators. However, according to our research, the treatment has no effect on approximately 25% of patients, and between 60% and 80% present no fundamental clinical improvement in their condition (ACR 70). In nine out of ten patients, no lasting remission occurs. Moreover, around half the patients stop taking the drugs within two years, because the efficacy diminishes or undesirable side effects become too pronounced. The medical need for developing new and more effective preparations is therefore very high.

The medical need for developing new and more effective preparations is very high. Based on estimates, the global market volume for the treatment of psoriasis amounted to USD2.8 billion in 2008. Currently, no treatment options are available that provide lasting remission.

Multiple myeloma, a bone marrow cancer, is incurable, with 95% of patients dying within ten years of diagnosis. In Europe, the estimated frequency of the disease is 25 per 100,000 inhabitants. According to the specialist magazine, Nature, the global market volume for multiple myeloma treatment is likely to be worth in the region of USD3.0 billion in 2009. The proportion of biotechnologically produced agents for the treatment of cancer patients is also rising rapidly. Last year, a volume of around USD1.6 billion was generated with the three most frequently used drugs.

It is generally expected that the global market for therapeutics used to treat systemic lupus erythematosus, the lead indication of BT-063, will rise sharply in the coming years. The reason is the approval of superior quality biopharmaceutical products, such as BT-063, which are currently still being developed. For 2012, we anticipate a market volume in excess of USD2.0 billion.

# **Regulatory environment**

In Europe, monoclonal antibodies are approved by a centralised procedure carried out by the EMEA. National authorities with the relevant expertise are involved in this process.

As is the case for Plasma Proteins, the competent control and approval authorities for biotherapeutics are the Paul Ehrlich Institute, the regional board in Darmstadt in Germany and the FDA in the USA. The FDA's Food, Drug and Cosmetics Act also applies to biotherapeutics.

Biotest is developing an agent for the treatment of a so far uncurable type of cancer.

# Strategy

# Group

The Biotest strategy is directed at expanding the Group's position as a global specialist for innovative immunology and haematology. The strategic cornerstones, internationalisation of business and strengthening Biotest's position as a quality provider, apply across all segments. Research and development are pivotal throughout the company.

### **Ethical value**

Biotest products are used in critical clinical areas. The quality of the products, the production processes, research and development as well as the sales organisation, and indeed every aspect of the company, must respond to the most exacting demands. This impacts on the way in which production is structured as well as on the selection, basic qualifications and further training of our employees.

# **Plasma Proteins segment**

#### Internationalisation

Our aim is to expand the sales platform for our Plasma Proteins successively. To achieve this, we aim to gain approval for our products in all the major European markets. For products which have already received approval, we intend to succeed via the decentralised approval system as part of the mutual recognition procedure and for candidates in the development pipeline, the route of centralised European approval is open.

BPC is to expand its position in the highly attractive US market. In the first instance, the focus is on obtaining approval for the polyspecific intravenous immunoglobulin currently under development. In addition, we intend to enhance the range of products offered in the USA with specific Plasma Proteins developed and manufactured in Dreieich. We are also investigating whether approval of Nabi HB<sup>®</sup> in countries outside the USA would offer value added for Biotest.

Expansion is linked to continuous adjustments to the sales organisation.

### Expansion of the product range

By gaining approval for additional Plasma Proteins, we are complementing our range of products in this segment. Examples of Plasma Proteins in the development pipeline include an IgM concentrate, a hyperimmunoglobulin for prophylactic treatment of hepatitis C positive patients following liver transplantation and a polyvalent immunoglobulin (the latter for approval in the USA). Moreover, we aim to replace some products which up to now have been bought in under licence agreements with proprietary products Our aim is to expand the sales platform for our plasma proteins successively.

By gaining additional approvals, we are complementing our range of products.

# Development of existing products

With regard to existing products, we aim to obtain approval for additional indications. At the same time, we are working on optimising the safety and tolerability profile and developing application forms that are more pleasant for patients. As far as the latter is concerned, this means, for example, further developing immunoglobulins which to date have only been administered intravenously to make them suitable for subcutaneous administration (injection below the skin). Patients can administer such preparations themselves, whereas intravenous injections may only be given by doctors or specially trained staff.

# Demand-driven capacity development

Currently, Biotest is in a position to fractionate a volume of approximately one million litres of blood plasma per year in its own facilities and by accessing partner capacities. We intend to increase the Group's annual fractionation capacity up to 1.4 million litres by setting up and gaining approval for a fractionation plant in Boca Raton. We will also increase capacity accordingly in the further processing steps of Plasma Proteins production.

# Ensuring the supply of raw material

Biotest's aim is to obtain approximately half of the plasma processed annually from its own plasmapheresis centres and buy in the other half. In this way, we ensure that the supply of raw materials is sufficient at all times, making us less dependent on price developments in the global market. In addition, we can manage the volume of available plasma more flexibly and respond better to possible fluctuations in demand. BPC is to cover its requirement in full from its own sources.

# Establishment of a production network

We are in the process of combining our production capacity in Europe and USA. In the first instance, blood plasma obtained in the USA will be processed at our Dreieich facility. The second step will involve the delivery of intermediates from the fractionation plant in Boca Raton to Germany. In the final phase, the production sites in Europe and the USA will have mutual approval in the respective other market.

The facility in Boca Raton will also be expanded to include the production of monoclonal antibodies. Biotest intends to establish a second production unit for the Biotherapeutic segment there, alongside the production taken on by toll manufacturers.

# **Microbiological Monitoring segment**

# Internationalisation

In the Microbiological Monitoring segment, we are aiming to expand our market position in the USA, Europe and Japan. These are markets in which we will be significantly gearing up our sales efforts.

We intend to increase the annual fractionation capacity up to 1.4 million litres.

Biotest's aim is to optain approximately half of the plasma processed from own centers.

# Development of new target groups

Alongside the pharmaceutical industry, our intention is to win over more customers from the food and cosmetics industries. Our core target group comprises the major multinational groups. The demand for our products in the biopharmaceutical sector (pharmaceutical products, which are produced on the basis of cell cultures) will continue to increase, since this sector within the pharmaceutical segment is experiencing marked acceleration in growth.

# Expansion of position as quality and innovation leader

In research and development, we focus on innovative technologies which will expand our position as an innovation leader. System-based thinking – media, equipment, software and evaluation options – will gain importance in the future. The relevant projects relate, for example, to combining microbiological test procedures with automated solutions. In this respect, we work with specialist systems development companies. Where terms and conditions are favourable, the acquisition of companies may prove a way for us to grow faster. Potential acquisition candidates are other providers of microbiological test systems and small companies in the software and systems development sector.

# **Medical Diagnostics segment**

# Internationalisation

In the Medical Diagnostics segment, the planned internationalisation of business will also focus primarily on the US market. Following the FDA approval granted in 2008 for manual reagents, we are now one of only three providers of transfusion diagnostics in the USA. We intend to use the established sales structure of the Biotest Diagnostics Corporation to rapidly develop a major customer portfolio. With our products, we offer system solutions in transfusion diagnostics mainly for the small and mediumsized hospital segment.

#### Focus on core products

Given the fierce competition in the market for immunological diagnostics, Biotest will focus on sectors with high quality requirements and/or those which are subject to stringent approval criteria. Production will centre on manufacturing high-margin products and/or large volumes. The production of all other product lines will be outsourced to third parties.

#### **Cooperation agreements**

The search for a strategic partner is of highest priority in this business division. Biotest is willing to consider the establishment of a joint venture, including as a minority shareholder, or acquiring smaller competitors.

The acquisition of companies may prove a way for us to grow faster.

The search for a strategic partner is of highest priority.

# Research and development

In recent years, all internal resources have been geared to market entry in the USA. Having achieved this, the company will now focus on developing innovative diagnostic products.

# **Biotherapeutics segment**

### Focus on lead indications

In the Biotherapeutics segment, the focus is on value-oriented continued development of monoclonal antibodies. In order to tap significant sales and profit potential, we shall initially be concentrating on indications with a high patient prevalence and/ or particularly high demand for treatment.

### Cooperation with major pharmaceutical companies

Biotest intends to progress the mAb development up to clinical Phase II for its own account. However, from the cost-intensive clinical Phase III onwards, our intention is to continue development in cooperation with global partners in the pharmaceutical or biotech sectors. Our aim is to achieve rapid worldwide development and approval. While Biotest intends to retain co-marketing rights for Europe and other individual markets, the partner would have the option of obtaining exclusive distribution rights in other regions.

Potential partners would have to make upfront and milestone payments for acquiring the relevant licences. In addition, Biotest would share in any subsequent revenue of the partner via royalties.

#### Establishment of proprietary production of monoclonal antibodies

Biotest has started to expand a facility for the production of monoclonal antibodies at the Biotest Pharmaceuticals Corp. site in Boca Raton. It will complement the capacity secured under long-term agreements with toll manufacturers.

# Value-oriented corporate management

The management of Biotest is determined by financial, as well as non-financial factors, each of which impacts differently on the value of the company. The financial and non-financial performance indicators are the subject of regular reports.

#### **Financial management indicators**

The financial statistics of the company referring to the Group as a whole are return on capital employed (RoCE) and at segment level, earnings before interest and tax (EBIT). Cash flow is also one of the main indicators in the company's finances.

We will concentrate on indications with particulary high medical need. The values of these indicators for 2007 and 2008 are provided in the relevant sections of the explanations on the earnings position and the financial position and statement of assets.

In addition, we also carry out ongoing analysis of the costs of goods sold, marketing and sales, research and development, as well as the profit/sales ratio and the structure of accounts receivable, including any inherent risks.

#### Non-financial indicators

The major non-financial performance indicators for the Group as a whole are the capacity utilisation in production, the production run and downtimes as well as the level of stocks held along the production chain. In Plasma proteins production, we also monitor the yield per unit of plasma and the level of supplies obtained from our own sources. Where sales are concerned, the important indicators are the Biotest share of the market as a whole or the market segment concerned, the number of customers for each product (sales depth), the sales and profit margin achieved per capita of sales personnel and the comparative figures.

For reasons of competition, Biotest refrains from publishing these indicators.

Research and development projects are steered by means of milestone plans. Segment managers and the Board of Management are kept informed in regular project progress reports.

# Market environment

#### **Macroeconomic developments**

Developments in the economic environment as a whole were dominated by the consequences of the international crisis in the financial markets. The high level of liquidity injected into the banking sector by central banks and government rescue packages prevented the total collapse of the global financial system. However, the viability of the financial markets was subject to substantial disruption in the second half of the year.

In addition, there have been increasing signs that the major national economies in the world are entering a recession. In Germany, a considerable downturn in GDP was recorded from the second quarter of 2008 onwards. Thanks to the strong first quarter, growth for the full year amounted to 1.3% compared with 2.5% in the previous year. GDP for the 15 eurozone countries rose by only 1.0% in 2008, after growth of 2.6% in 2007. In the USA, economic growth amounted to 1.1% last year (2007: 2.0%).

The sector economy of the pharmaceutical industry remained largely unaffected by the financial crisis in 2008. Accordingly, last year's events have had no impact on the business of the Biotest Group so far.

Last year, the US dollar gained approximately 5.5% in value against the euro. On 31 December, the price for  $\leq$ 1 was USD1.39 while 12 months earlier the exchange rate was USD1.47.

The first two quarters of the reporting year were marked by further gains of the euro against the US dollar. However, from the middle of the third quarter, the trend reversed and in the fourth quarter, the exchange rate fell below the USD1.30 mark at times. As of the year-end, the US currency recorded a further substantial loss.

In financial year 2008, Biotest generated approximately 20% of consolidated sales in US dollars. Since we also obtain a considerable proportion of our preliminary products and services in US dollars, exchange rate fluctuations did not impact on income in full.

# Plasma Proteins segment

According to estimates by data provider, MRB, the sales volume in the global Plasma Proteins market amounted to USD12.8 billion last year, which represents a rise of around 8.5% on 2007 (USD11.8 billion).

Demand for immunoglobulins increased once again in the year under review by an estimated 10%. The rise was essentially driven by new indications. The European Academy of Dermatology and Venereology (EADV) has included high-dosage treatment with immunoglobulins for bullous skin diseases (e.g. pemphigus) in its treatment recommendations. Demand for coagulation factors and albumin remained stable.

On the other hand, the available supply of Plasma Proteins increased considerably year-on-year. This reflected the fact that companies in this sector have significantly expanded their capabilities for obtaining plasma. According to data from sector association PPTA, the volume of human blood plasma available for processing was approximately 20% higher at the end of last year than 12 months earlier.

The surplus demand, which has dictated the situation in the global market in recent years, shrank in 2008. In individual markets, for example Germany, the UK and Austria, supply and demand were balanced as of the year-end.

This affected the price trend for end products. In particular with regard to albumin, the first price decreases were evident in the developed markets as of the year-end. In terms of the year as a whole, however, the price level for all Plasma Proteins was higher than in the previous year.

The rise of demand for immunoglobulins is driven by new indications. With regard to deliveries to emerging markets, there were still numerous opportunities as these continued to be marked by significant surplus demand.

In Western Europe, the trend towards consolidation on the demand side persisted. In Germany, further hospitals joined forces by forming purchasing pools, which puts them in a stronger position during price negotiations. Today, around 40% of Plasma Proteins supplied to hospitals are purchased by such pools. In the UK, the authorities have introduced a Demand Management Programme, with a panel of doctors deciding which patient groups should predominantly be given immunoglobulins.

With regard to cost reimbursement by state health systems, there were no major changes during the reporting year. Some European countries are considering whether to follow Germany's example and oblige manufacturers of pharmaceutical products to give a discount on drugs sold under the state reimbursement of costs scheme.

### Microbiological Monitoring segment

Companies in the pharmaceutical industry faced the task in 2008 of meeting the ever more stringent requirements in terms of production and hygiene monitoring by developing efficient and safe procedures. Consequently, interest increased in automated and system solutions for this segment. Customers are increasingly interested in safer and more efficient test methods, such as the data matrix code on Biotest's plates and agar strips. Ahead of harmonisation of the guidelines on test media used in non-sterile production areas, companies carried out a more intensive review of which media they use for hygiene monitoring.

Since the amended guidelines anyway necessitated validation of the media used, various parties were more willing to consider a change in supplier. These circumstances impacted favourably on sales opportunities for Biotest products last year.

#### Medical Diagnostics segment

As was the case in previous years, the European transfusion and transplantation diagnostic markets were marked by extreme competitive pressure. At a time of stagnant overall demand, the process of concentration on the customer side and the aggressive approach of individual providers resulted in the achievable prices remaining unchanged, or even decreasing again in some cases.

In the USA, demand remained consistent. Given the fact that competitive pressure among providers is low, the price level was maintained at a considerably higher level compared with the global market.

Customers are increasingly interested in safer and more efficient test methods.

# **Biotherapeutics segment**

Information about the relevant markets is provided in the section "Business and general conditions". Biotest dispenses with a description of developments in the market during the reporting year, since we do not expect approval for monoclonal antibodies before 2012 at the earliest.

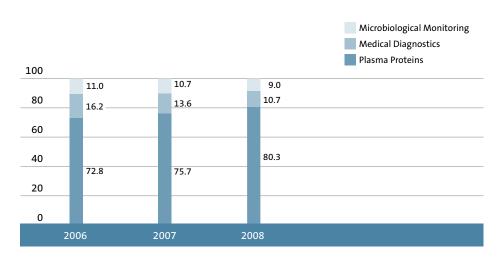
# **Business development**

In financial year 2008, Biotest achieved a significant increase in sales compared with the previous year. Net of the contribution made by the Plasma Proteins activities in the USA, which were acquired at the end of 2007, sales growth was also strong.

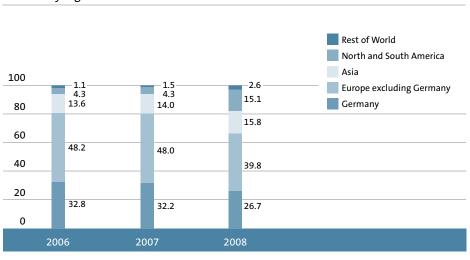
€ million	2008	2007	Change in %
Group revenue	423.0	326.4	+29.6
excluding BPC contribution	358.9	326.4	+10.0
Plasma Proteins	339.5	247.0	+ 37.4
excluding BPC contribution	275.4	247.0	+11.5
Medical Diagnostics	45.2	44.3	+ 2.0
Microbiological Monitoring	38.3	35.1	+ 9.1

The focus of the Biotest Group's business activities remained on Europe in 2008. In these markets, Biotest achieved sales totalling  $\leq 281.4$  million after  $\leq 262.0$  million in the previous year (+7.4%). Germany was the largest single market once again, where sales grew by 7.3% to  $\leq 113.0$  million (previous year:  $\leq 105.3$  million).

Sales after segment in %



The America sales region gained significantly in importance. Biotest achieved sales amounting to  $\leq 63.9$  million there, which represents an increase of 356.4% on the previous year ( $\leq 14.0$  million). Excluding the contribution made by BPC, the business volume achieved in the USA was still up 22.9% on the previous year's figure. In the Asian markets, sales totalled  $\leq 66.9$  million (+46.7%) and in the remaining markets worldwide the volume of business rose by 125% to  $\leq 10.8$  million.



# Revenue by region in %

#### **Plasma Proteins segment**

The highly successful Plasma Proteins business was again the main growth driver in the Group as in the previous year. Growth was recorded across all sales regions and product groups (cf. table) and was based on quantity as well as price. In 2008, Biotest succeeded in implementing further price increases for most product groups in the market.

In the Plasma Proteins segment growth was recorded across all sales regions.

#### Plasma Proteins: revenue by product group

€ million	2008	2007	Change in %
Immunoglobulins	126.4	106.7	+18.5
Coagulation factors	81.2	78.8	+ 3.0
Albumin	25.2	20.2	+24.8
Toll manufacturing	18.7	10.9	+ 71.6
Plasma <sup>1)</sup>	44.0	0.0	-
Other <sup>2)</sup>	44.0	30.4	+ 44.7
Total	339.5	247.0	+ 37.4

<sup>1)</sup> Including sales relating to plasma deliveries of BPC to third parties under existing agreements, which were taken over from Nabi Biopharmaceuticals

<sup>2)</sup> Including Biseko<sup>®</sup> and merchandise

In the financial year 2008, the success of Intratect<sup>®</sup> was ongoing.

In the USA we defended the positioning of Nabi HB<sup>®</sup>.

Business with the polyvalent immunoglobulins Intratect<sup>®</sup> and Intraglobin<sup>®</sup> continued to record very strong growth, with sales in 2008 increasing by 26.8%. This resulted from the ongoing success of Intratect<sup>®</sup> in markets such as Germany and the UK as well as the launch of sales in additional countries, including Switzerland. In Greece, we significantly reduced Intraglobin<sup>®</sup> sales. In view of the very low level of costs reimbursed as part of the state health system, it was more attractive to use the available volume of the preparation to service other markets where margins are higher.

With regard to hyperimmunoglobulins, the sales growth of 6.5% for Hepatect<sup>®</sup> was particularly noteworthy in 2008. The increase is mainly attributable to the approval of the preparation in additional European countries, granted in April as part of the MR procedure. Among these countries is the UK, where Hepatect<sup>®</sup> is the first intravenously administered immunoglobulin approved for prophylactic treatment of hepatitis B. In December 2008, we submitted the documentation for approval of Hepatect<sup>®</sup> FH, manufactured with the filter aid procedure, in major European countries.

In the USA, we defended the positioning of Nabi HB<sup>®</sup> as the leading product for prevention of hepatitis following liver transplantation. The market share was just over 50% in 2008. In the financial year under review, sales were not significantly affected by the fact that in March 2008, the FDA granted orphan drug status to a competitor product for the prophylactic treatment of hepatitis in liver transplantation. Most users continued to prescribe Nabi HB<sup>®</sup> in this indication for off-label use, since unlike its competitor, the Biotest preparation is sugar-free and therefore offers medical advantages.

There was a downward trend in revenue from Pentaglobin<sup>®</sup>. The reason for this was the limited availability of the product in financial year 2008.

Biotest achieved a sales increase in coagulation factors compared with the previous year. In Russia, we successfully expanded business volume on the strength of high-volume orders for the delivery of coagulation factor VIII, which resulted in the corresponding higher sales volume of Haemoctin<sup>®</sup>.

The sharp rise in albumin sales was partly accounted for by a marked increase in quantity. In view of the high level of demand, we processed preliminary products and intermediates which were produced in 2007 and marketed them as end products.

Sales based on toll manufacturing were up as a result of expanded business with countries in the Asia sales region.

Biotest posted further success in the internationalisation of its Plasma Proteins business in the reporting year. In addition to the mentioned licence to sell Hepatect<sup>®</sup> in further European countries, we gained approval for Intratect<sup>®</sup>, which is produced on the basis of an expanded manufacturing process. Purification has been enhanced by a further safety stage, nanofiltration, as is also the case in the production of Hepatect<sup>®</sup>. This created the precondition making the application for approval of both preparations in France and Spain possible. With regard to coagulation factors, we completed our range of products with the approval of Haemonine<sup>®</sup>, the factor IX preparation for treating type B haemophilia, which was granted in November 2008. The approval procedure for Haemoctin<sup>®</sup> was successfully concluded in the UK and other countries as early as March 2008.

Expansion of the approval for Biotest-produced albumin to include additional European countries as part of the MR procedure was completed successfully at the end of December 2008.

In the USA, the work associated with integrating BPC into the Group was completed within a few months. All the licences required to produce and market Plasma Proteins in the USA were transferred from Nabi Biopharmaceuticals to BPC.

Headed by Chief Executive Officer (CEO) Dr. Rainer Pabst, the management team comprises employees from the USA and Germany. All activities relating to the development and approval of Plasma Proteins in the USA have been pooled in Boca Raton and the teams have been expanded as required. In addition, we completed all the preliminary work required for the planned expansion of Plasma Proteins production.

In 2008, we considerably increased our European production capacities. The second facility for chromatographic purification launched operations in Dreieich in September 2008. This enables us to produce four instead of two tonnes of immunoglobulins per year from 2009 onwards. In December 2008, we concluded an agreement with Belgian company C.A.F.-D.C.F. It provides us with access to an annual fractionation volume of approximately 300,000 litres over a period of ten years. The capacity available to Biotest has therefore increased to more than one million litres per year.

Since 1 May 2008, the Dreieich facility has operated a non-stop triple-shift system in fractionation, working around the clock, seven days a week.

The number of plasmapheresis centres operated by Biotest rose to 20 worldwide by the end of the financial year following the opening of new centres in Budapest, Iowa City and Nordhausen. Half of the centres were based in Europe and the other half in the USA. A further centre was acquired in the USA in January 2009. Of the blood plasma processed in the last financial year, more than 40% originated from the company's own collection stations.

In Germany, Biotest's most important market for Plasma Proteins, the sales operation has been restructured and divided according to region. This enables us to maintain closer customer relationships, especially with regard to key accounts. The work associated with integrating the BPC was completed within a few months.

The Dreieich plasma fractionation facility is working around the clock, seven days a week.

# **Microbiological Monitoring segment**

Sales growth in the Microbiological Monitoring segment was largely attributable to the success of products from our affiliated company heipha Dr. Müller GmbH in financial year 2008. We recorded a particularly sharp rise in business with test plates used for monitoring sterile environments. Growth in the business volume of products from the HYCON series was moderate.

The sales increase was mainly attributable to the higher quantity sold while prices remained largely stable

€ million	2008	2007	Change in %
Biotest HYCON	12.0	12.6	- 4.8
heipha	25.2	21.4	+17.8
Merchandise	1.1	1.1	0.0
Total	38.3	35.1	+9.1

# Microbiological Monitoring: revenue by product group

Biotest recorded particularly strong growth in Germany and in the markets serviced by its affiliated companies. Following the approval of our products in the USA, granted in 2007, we focused on building up a customer base last year. The first major pharmaceutical companies have already opted for our products.

However, overall we have realised that it takes longer than expected for companies to switch to a new provider for their hygiene monitoring requirements due to the necessary validation of the products.

The practice implemented by global pharmaceutical groups of standardising the media used to monitor hygiene within the relevant company has resulted in enquiries for us from countries in which Biotest HYCON and heipha Dr. Müller GmbH have not been represented to date, including India and Australia.

In Production and Development, Biotest pooled its resources in 2008, opening a technology centre in Eppelheim in June 2008, which combines the development, production and marketing of Biotest HYCON. The centre is very close to the location of heipha Dr. Müller GmbH.

In order to strengthen Biotest's presence in its core markets and consistently develop new growth regions, the company has expanded its sales structures. In Japan, a direct sales team has been set up and two area managers have been employed, one for the markets of South East Asia and one for those in Central and Eastern Europe.

# **Medical Diagnostics segment**

The slight increase in sales of transfusion diagnostic products more than compensated for the sharp decline in the area of transplantation and other products.

### Medical Diagnostics: revenue by product group

€ million	2008	2007	Change in %
Transfusion diagnostics	19.8	18.0	+10.0
Transplantation diagnostics	9.6	10.9	- 11.9
Infection diagnostics	6.7	6.7	0.0
Merchandise	9.1	8.7	+4.6
Total	45.2	44.3	+ 2.0

Last year, there were obvious signs of a gradual improvement in the segment's situation. Business in the USA mainly accounted for this positive development. As of the 2008 year-end, 50 TANGO® optimo systems were in use in the USA, twice the number recorded at the end of 2007.

The sales opportunities for this automated blood group diagnostic system improved considerably in the USA in 2008. In August, the FDA approved 39 products for manual blood group diagnostics. Since then, Biotest has been in a position to operate as a full service provider for immunohaematological products in the USA and fully exploit the potential offered by this attractive market. This included the conclusion of a long-term framework agreement with the association of 77 blood banks.

In Germany, our most important sales market, we gained additional key customers for our transfusion diagnostic systems, such as the LBK Group.

As in previous years, transplantation diagnostic business was affected by difficult market conditions.

The establishment of Biotest Medical Diagnostics GmbH coupled with the move into a new building in March 2008 completed the organisational and physical separation of our immunology activities from the other Group operations. The new location near the Group headquarters in Dreieich comprises a second production line, research and development laboratories and offices for the sales organisation and administration. The search for a strategic partner in the Medical Diagnostic segment continued during the reporting year. Although extensive talks and negotiations took place, they yielded no agreement due to differences about the valuation approach and strategic management.

In November 2008, the regular inspection of the production facilities in Dreieich by the FDA, which is conducted every two years, produced no objections worth mentioning.

#### **Biotherapeutics segment**

Developments in this segment during the financial year under review are described in the relevant part of the "Research and development" section.

The sales opportunities for TANGO<sup>®</sup> optimo improved considerably.

# **Earnings position**

# Key profit and return figures

Similar to the previous year, the Biotest Group achieved stronger growth in income than sales in financial year 2008. The EBIT and EBT figures excluding the contribution from the US Plasma Proteins business mark record levels in the company's history.

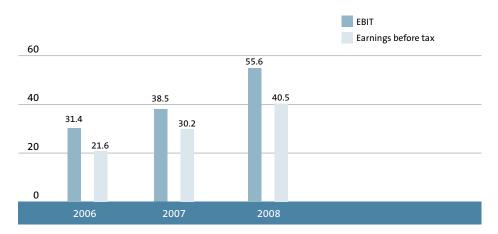
# Performance indicators for the Biotest Group

€ million	2008	2007	Change in %
EBIT	55.6	38.5	+44.4
excluding BPC contribution	49.6	40.0	+24.0
EBT	40.5	30.2	+34.1
EAT	28.1	17.3	+62.4

The rise in income is mainly based on the success recorded in the Plasma Proteins segment. As with sales growth, the upward trend in income is primarily based on the success recorded in the Plasma Proteins segment. EBIT in this segment amounted to  $\in$ 81.2 million, representing an increase of around 33.6% on the previous year ( $\in$ 60.8 million). Excluding the BPC profit contribution of  $\in$ 6.0 million, the segment achieved EBIT of  $\in$ 75.2 million, which corresponds to a rise of 20.7% compared with the figure for 2007. The margin achieved on the basis of a higher sales volume accounts for this rise.

EBIT in the Microbiological Monitoring segment was up slightly from €4.8 million to €5.0 million (+4.2%). This increase was also primarily attributable to the rise in sales achieved.





With EBIT of  $\leq$ -3.3 million, Medical Diagnostics remained in the red. However, compared with the previous year ( $\leq$ -6.3 million), the segment achieved a significantly better result. It should be noted that the figure for 2007 was affected by non-recurring personnel measures as part of the restructuring of the segment. The result for 2008 includes expenses in connection with US market entry.

EBIT for the Biotherapeutic segment of €–16.7 million takes account of the expenses for the R&D projects pooled there. In the previous year, EBIT for this segment amounted to €–14.7 million.

The return on sales determined on the basis of EBIT was 13.1% at Group level, following 11.8% in 2007. The return on capital employed (RoCE) amounted to 10.4%. In the previous year, this figure was 7.8%. The marked rise is attributable to the fact that BPC contributed to the Group's income for the full 12-month period in 2008.

Major return indicators markedly improved as compared to last year.

#### Expenses

#### Key cost pools of the Biotest Group

€ million	2008	2007	Change in %
Goods sold	203.9	153.8	+ 32.6
Distribution	81.0	72.1	+12.3
Administration	40.2	26.0	+ 54.6
Research and development	43.7	34.5	+26.7
Balance of other operating income and expenses	1.4	0.0	_
Financial result	-15.1	- 8.2	_
Income tax expense	-12.4	-12.9	-

With regard to the increase in the Group's cost pools, it should be noted that in 2008 the individual items also comprised the relevant figures for Biotest Pharmaceuticals Corporation for the first time.

The largest cost pool at Biotest is the cost of goods sold. In 2008, this rose sharply as a result of growth. The cost of sales ratio improved slightly compared with the previous year to 48.2% (2007: 47.1%).

The upward trend in the distribution expense is also mainly due to the inclusion of the Biotest Pharmaceuticals Corporation. The expansion of the sales organisation also accounts for part of the increase.

The sharp rise in the administrative expense resulted essentially from high non-recurring costs in connection with the introduction of SAP as the standard software in Germany and the cost of seconding employees to international subsidiaries. The newly added administrative expense of BPC should also be taken into account in this respect.

The higher research and development expense includes the cost of expanding project teams as well as start-up costs for constructing the facility to produce monoclonal antibodies in Boca Raton. Of total costs,  $\in$ 24.0 million was attributable to the Plasma Proteins segment (previous year:  $\leq$ 16.6 million),  $\leq$ 16.6 million to the Biotherapeutics segment (previous year:  $\leq$ 14.2 million) and  $\leq$ 1.6 million and  $\leq$ 1.5 million respectively related to the Microbiological Monitoring and Medical Diagnostics segments (previous year:  $\leq$ 1.9 million and  $\leq$ 1.8 million).

Other operating income of €6.9 million (previous year: €6.5 million) resulted largely from exchange gains, deferrals and writing back provisions. This was offset in 2008 by other operating expenses amounting to €5.5 million (previous year: €6.5 million), of which exchange losses totalling €1.7 million represented the single largest item. VAT expenses of €0.2 million, which resulted from a tax audit, are also included in other operating expenses.

The financial result was impacted by the higher interest expenses relating to the loans raised to finance the BPC acquisition.

With regard to the income tax expense, it should be noted that the previous year's figure was affected by non-recurring factors resulting from changes in tax legislation. Compared with 2007, the tax ratio decreased from 42.7% to 30.6% in 2008.

# Financial position and statement of assets

In financial year 2008, the Biotest Group had sufficient financial resources at all times. The ratio between equity and liabilities remained stable in the course of the year.

Biotest has access to secure long-term debt financing. The loan agreement concluded in connection with the acquisition of the US Plasma Proteins business in autumn 2007 runs until 2014 and 2015 respectively. The financing commitment totalling €175.0 million comprises €135.0 million in long-term loans, which were utilised in full in financial year 2008.

In the event of a change in the majority of shares with voting rights, the agreement with the syndicate banks provides an extraordinary cancellation clause, which would make it necessary to re-negotiate the financing with the involvement of the new majority shareholder, if applicable.

The remaining amount of  $\leq$ 40.0 million is attributable to a revolving short-term credit line to finance current assets. This was most recently extended by one year on 6 November 2008.

A detailed description of the maturity pattern of the loans is provided in the notes to the consolidated financial statements.

Biotest has access to secure long-term debt financing.

#### **Balance sheet**

At €592.0 million, the Biotest Group's balance sheet total was considerably higher as of 31 December 2008 than in the previous year (€536.7 million).

# Selected figures from the Biotest Group's balance sheet

€ million	2008	2007	Change in %
Assets			
Property, plant and equipment	229.9	214.2	+7.3
Intangible assets	73.8	73.4	+ 0.5
Inventories	156.6	116.9	+ 34.0
Trade receivables	94.5	101.1	-6.5
Cash and cash equivalents	8.1	8.9	-9.0
Equity and liabilities			
Equity	253.4	225.8	+12.2
Non-current financial liabilities	166.6	162.7	+2.4
Current financial liabilities	28.2	26.1	+ 8.0
Trade payables	48.7	32.1	+ 51.7

The fact that the balance sheet has been stretched on the assets side is primarily attributable to a higher level of current assets. This is essentially due to significantly higher inventories which resulted from the company's growth.

The substantial expansion of production in the Plasma Proteins segment was associated with higher demand for raw materials and supplies. The volume of work in progress recorded as of the reporting date also rose substantially. In this way, we ensured that our stocks of products were sufficient when entering new markets and we were able to deliver at any time. The manufacturing process for Plasma Proteins involves longer periods of time, in particular due to the testing periods prescribed by drug legislation, and the relevant long-term arrangements therefore need to be in place.

In the Microbiological Monitoring and Medical Diagnostics segments, we have stockpiled products as appropriate ahead of market entry and/or the launch of sales of manual reagents in the USA.

Despite the growth in sales, we were able to reduce the volume of trade receivables compared with the previous year. This decrease resulted from higher sales of accounts receivable as part of factoring Accounts receivable from business with customers in Russia (essentially relating to sales of coagulation factors) were hedged almost in full as of the reporting date.

Despite the growth in sales we were able to reduce the volume of trade receivables. On the liabilities side, the increase in equity, largely attributable to consolidated net profit for the year and the fact that currency differences are posted without impact on income, resulted mainly from currency translation relating to the US subsidiaries. Current liabilities increased in line with growth as a result of higher payment obligations relating to trade payables in connection with the company's growth.

The rise in financial liabilities is largely attributable to exchange rate effects. The higher rate of exchange of the US dollar against the euro in the course of the year meant that the volume of the loans held by BPC in US dollars increased if translated into euros.

The Biotest Group's equity ratio rose slightly from 42.1% to 42.8% compared with the previous year.

Capital expenditure, depreciation and amortisation

In the financial year under review, Biotest's capital expenditure amounted to €36.5 million. In the previous year, this figure stood at €151.9 million as a result of the acquisition of the US Plasma Proteins business.

Capital expenditure on property, plant and equipment in 2008 accounted for €31.9 million (87.4%), while Biotest invested €4.6 million in intangible assets.

Major items included the completion of the complex of buildings and the second production line of Biotest Medical Diagnostics GmbH as well as investment in expanding the Plasma Proteins segment. This included, in particular, the construction of a pilot plant for manufacturing IgM concentrate, which is currently under development.

heipha Dr. Müller GmbH started construction of a new warehouse at the Eppelheim location, in order to adjust capacity there to the higher production volume. In addition, new facilities for filling and labelling test tubes and plates were set up. These facilities make it possible to apply data matrix codes to products.

In Dreieich, Biotest acquired two plots of land with a total area of 5,000 square metres, which will be held as a reserve for possible future expansion of the site.

The SAP software introduced at the start of 2008 was enhanced in the following months to include additional functions.

In the Plasma Proteins segment, we have started to define a framework plan for the expected investment required in the coming ten to 15 years.

The Biotest Group's equity ratio rose slightly from 42.1% to 42.8% compared with 2007. Capital expenditure was offset by depreciation and amortisation of €26.2 million (previous year: €16.4 million), of which the majority stemmed from scheduled depreciation and amortisation, as was the case in the previous year. The increase of 59.8% compared with 2007 is essentially attributable to the fact that assets rose sharply following the acquisition of BPC.

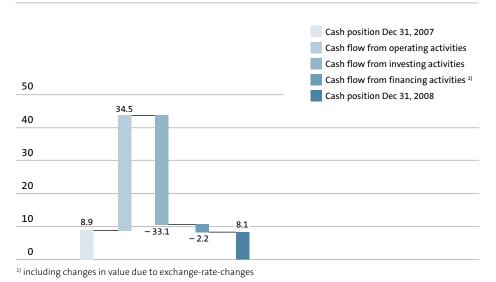
Projects underway and contractually fixed projects will incur expected capital expenditure of  $\leq$ 4.3 million in 2009 and 2010. This is divided between the following major items: the expansion in energy supply ( $\leq$ 1.5 million), the GMP upgrade of the human albumin filling facility ( $\leq$ 1.0 million) and the expansion of immunoglobulin production ( $\leq$ 1.8 million).

#### **Cash flow statement**

In 2008, the cash flow from operating activities amounted to €34.5 million, representing a rise of 21.1% on the previous year's figure (€28.5 million). While pre-tax profit saw a marked increase, current assets comprised a higher figure of tied-up capital. In the year under review, the outflow relating to investing activities totalled €33.1 million. The previous year's figure of €164.5 million reflected the acquisition of the US Plasma Proteins business. Net of this effect, the outflow of funds relating to investments amounted to €31.3 million in 2007. Compared with this figure, the increase in 2008 was 5.8%. Investments in 2008 were funded in full from internal resources.

Cash outflows from financing activities totalled €2.3 million. In the previous year, this item included an inflow of €136.1 million as a result of the financing for the US acquisition.

#### Cash flow statement in € million



Investments in 2008 where funded in full from internal resources.

# Summary by the Board of Management regarding the earnings, financial and assets position of the company

In financial year 2008, Biotest continued the profitable growth of previous years. The contribution made by the US Plasma Proteins business acquired at the end of 2007 propelled the company into a new dimension in this segment. We also achieved significant progress in the other segments with regard to the planned expansion of our position in the USA. Biotest has continued with the internationalisation of its own business, providing a broader and more stable basis for its activities. Investments in capacity expansion and expenses for research and development are aimed at consolidating the position we have gained as a leading global specialist in immunology and haematology in the long term.

By hiving off the business activities relating to medical diagnostic products and setting these up as Biotest Medical Diagnostics GmbH, we have optimised the corporate structures. Growth in income in financial year 2008 indicates that this measure has significantly improved prospects for the segment.

The Biotest Group has sound financing. The equity ratio of 42.8% as of the reporting date and secured long-term credit lines ensured that Biotest was in a position to back growth in operating activities and key projects for the company's continued development with the required financial resources at all times. In the course of the financial year under review, no situation arose at any time that was prejudicial to the continuing existence of the company or its development opportunities.

BPC's contribution lead Biotest to a new dimension in Plasma Proteins business.

# **Research and development**

#### **Plasma Proteins segment**

In line with its corporate strategy, Biotest's focus in financial year 2008 in terms of research and development in the Plasma Proteins segment was on further developing products that have already been approved for additional indications and new forms of applications as well as complementing its range of products with the development of new products.

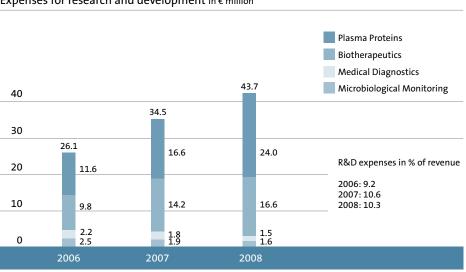
#### **Development of existing products**

Intratect®: In December 2008, the final report was available on the Phase III/IV trial for the use of the immunoglobulin in the indication of primary antibody deficiency syndrome. The results confirm the good efficacy and tolerability of the preparation. In the clinical Phase III trial for the indication fibromyalgia (chronic pain syndrome), all patients included in the trial had received the preparation over the envisaged period of time by the end of the financial year under review. The evaluation of the data collected is ongoing. Due to additional comprehensive laboratory analysis, the final report is not expected to be ready before the second quarter of 2009.

Zutectra®: The procedure for approval throughout Europe of the subcutaneously administered variant of the Hepatect® hyperimmunoglobulin started in October 2008 when we submitted the required documentation to the authorities. This is the first time Biotest has opted for the centralised approval procedure. Upon successful completion of the procedure, Zutectra® will be approved in all European Union countries.

In cooperation with Vetter Pharma-Fertigung GmbH & Co. KG, we completed validation of syringe filling with Zutectra® on the production scale in November 2008. The Ravensburg-based specialist in aseptic pre-filled application systems will supply syringes, enabling patients to inject themselves with Zutectra<sup>®</sup>.

Zutectra<sup>®</sup>, the preparation for hepatitis prophylaxis, shall be approved Europe-wide.



#### Expenses for research and development in € million

**Cytotect®:** We are developing the immunoglobulin for the indication of prevention of foetal cytomegalovirus infection (CMV) during pregnancy in women with primary CMV infection. The international trial requires that 15,000 to 25,000 pregnant women undergo immunoscreening, in order to obtain the 100 cases of primary infection during pregnancy specified for the trial. We recruited the first patients in 2008. As a result of the huge regulatory effort and the complexity of the project, it is behind schedule.

#### New developments

**IgM concentrate:** If approved, the high-dosage immunoglobulin will be used in the treatment of severe bacterial infections. In the reporting year, we set up the pilot facility for production of the clinical test preparation and produced the first batches required for pre-clinical development and Phase I of clinical development.

**Intravenous immunoglobulin (IVIG):** The development project of the Biotest Pharmaceuticals Corporation has progressed further. In May 2008, the last patient was included in the clinical Phase III trial. The trial is designed so that patients receive the preparation over a period of 12 months and are subsequently monitored for three months as part of a follow-up phase. It will not be possible to complete the final clinical report, which forms an essential part of the approval dossier, before the end of 2009.

**Civacir™:** After BPC acquired the development project in the indication of prophylactic hepatitis C treatment following liver transplantation, we carried out a thorough status analysis of the project. As a result, we have launched additional pre-clinical testing with the aim of standardising virus neutralisation in various manufacturing batches. Clinical development will then proceed. Biotest will launch a Phase III trial with the aim of being granted approval in the USA.

#### **Microbiological Monitoring segment**

In the year under review, the focus was on projects aimed at making processes in hygiene monitoring and their documentation safer and more efficient. To this end, we equipped additional products with data matrix codes at heipha Dr. Müller GmbH. The codes are read by a scanner which can also be used in sterile environments. The information collected can be transferred via an interface to standard data processing systems (for example LIMS) or processed using Biotest HYCON ID software.

The next development stage is fully automated, paperless documentation of hygiene monitoring in laboratories. In order to achieve this, we intend to integrate the heipha data matrix system and HYCON ID into one data maintenance and analysis software. For this purpose, we entered into a cooperation agreement with a specialist systems programming company last year.

In Microbiology, the focus is on projects aimed at making processes safer and more efficient. Furthermore, the research and development departments in the segment have worked on the new and continuing development of test media. One project, for example, involves the development of new test media for hygiene monitoring in antibiotics production facilities. With traditional procedures, there is a risk of residual antibiotics on the surface examined ending up in the test medium and consequently distorting the result by suppressing the growth of any bacteria that are present. The product from heipha Dr. Müller GmbH contains an enzyme which destroys antibiotics and reliably shows any contamination.

Last year, we developed tests to identify mycoplasma based on the principle of the polymerase chain reaction (PCR), making them ready for market launch.

#### **Medical Diagnostics segment**

In the Medical Diagnostics segment, we successfully concluded the development of the TANGO<sup>®</sup> multilink software in August 2008. The software is used for validation, management and documentation of results from blood group and antibody tests and cross-matching, and a key feature is that it operates independently of the diagnosis equipment used. Its unique feature is the possibility of validating results from blood group diagnostics via a secure internet platform anywhere in the world.

TANGO<sup>®</sup> multilink offers the unique feature of operating independent of site.

#### **Biotherapeutics segment**

The development of monoclonal antibodies progressed in financial year 2008. New milestones were achieved in each of the three projects.

#### Progress of pre-clinical and clinical trials

**BT-061:** Four clinical trials relating to the development of the antibody were underway last year in the indications of rheumatoid arthritis and psoriasis. Details about the design of the trials and progress in each case are provided in the following table:

Type of trial	Maximum dosage	Number of participants	Status in 2008
Phase I: Testing in healthy volunteers	Up to 60mg intra- venously and sub- cutaneously, single-dose	45	Completion with last participant in July 2008
Phase IIa : Rheumatoid arthritis	Up to 50mg sub- cutaneously and 12.5mg intravenously multi-dose, placebo-controlled	56	Patient recruitment ongoing
Phase I/IIa: Psoriasis	Up to 20mg intra- venously and 25mg sub- cutaneously, single-dose, placebo-controlled	56	Patient recruitment ongoing
Phase II: Rheumatoid arthritis	BT-061 and metho- trexate, intravenously, multidose, placebo- controlled	110	Patient recruitment ongoing

All of the data obtained in the trials during the financial year confirmed expectations regarding the good tolerability of the antibody. Indications are also promising with regard to efficacy.

The first blind analysis of data from the ongoing clinical Phase I/IIa trial in the indication of psoriasis was carried out in August 2008 and provided indications of the clearly positive efficacy of BT-061. After a single low-dosage treatment, there was a significant improvement in the clinical symptoms, with the effect lasting for more than two months. The trial also confirmed assessments regarding the safety and tolerability of the antibody. The Phase II clinical trial with BT-061 and methotrexate started in October involves preparations for the subsequent Phase III clinical trials.

**BT-062:** In August 2008, we launched clinical testing in four test centres in the USA. The Phase I clinical trial involves patients with multiple myeloma who have not responded to other treatment options or those who have suffered a relapse. In the initially administered low dosages, the tolerability of BT-062 in those patients who are worst affected was generally good.

**BT-063:** In the financial year under review, we advanced preparations for the clinical trial with the humanised antibody. The clinical test preparation was manufactured and we conducted toxicology trials.

#### Development of the patent situation

In the reporting year, Biotest expanded protection of its market exclusivity for monoclonal antibodies. Further patent applications have been submitted to the authorities in Europe, the USA and other potential sales markets for BT-061 and BT-062.

In its positive decision on an application for protection of market exclusivity for BT-061, the US Patent Office confirmed the innovative nature of the antibody.

The US authority, the FDA, granted orphan drug designation to the BT-062 antibody in the indication of multiple myeloma in March 2008 and the European Commission followed in December 2008. This status provides market exclusivity for up to seven (USA) and ten (European Union) years after approval for drugs which are being developed to treat rare and serious diseases.

The decision of the EU Commission was based on the assessment by the European approval authority, EMEA, that the use of BT-062 promises a significant improvement of the treatment options for multiple myeloma in terms of efficacy and safety.

#### Miscellaneous

Following completion of the facility conversion for the production of monoclonal antibodies at BPC in Boca Raton, pilot operations were launched in October. The site provides the option of installing a second fermentation plant to double capacity.

First analysis of data provided indications of the clearly positive efficacy of BT-061.

Orphan drug designation was granted to BT-062 by authorities in the USA and in Europe.

## Personnel

#### Growth in staff numbers

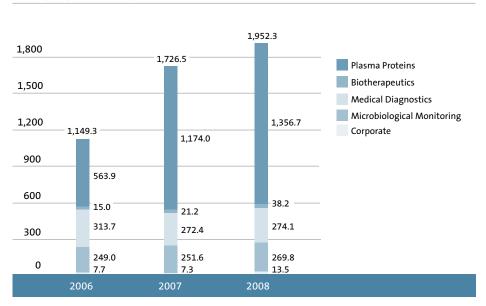
As of 31 December 2008, the Biotest Group employed 2,108 staff worldwide, which corresponds to 1,952.3 full-time equivalents. One year earlier, this figure amounted to 1,877 employees and a full-time equivalent of 1,726.5. The rise is primarily attributable to new staff members joining the Plasma Proteins segment. Here, the full-time equivalent rose from 1,174.0 to 1,356.7 in the reporting year. The increase reflected the opening of additional plasmapheresis centres in the reporting year and new jobs created in production in Dreieich and Boca Raton, as well as in the sales organisation at BPC. At the end of the year, the US company had 599 employees.

The number of jobs in the Microbiological Monitoring segment rose during 2008 from 251.6 to 269.8. New jobs were mainly created in the production and logistics departments of heipha Dr. Müller GmbH.

As of the end of the reporting year, the Medical Diagnostics segment had 274.1 fulltime equivalents (2007: 272.4). Of these, 133.9 full-time equivalents were attributable to Biotest Medical Diagnostics GmbH, which represents a decrease of 1.7 since incorporating partial operations into the company as of 1 January 2008.

As of the reporting date, the Biotherapeutics segment accounted for 38.2 fulltime equivalents (previous year: 21.2) and the Corporate segment for 13.5 (previous year: 7.3).

Just over half of the Group's employees (1,173.3 full-time equivalents) were based in Germany and around a third in the USA. Five employees from Germany were seconded to BPC and one employee from the USA was seconded to Germany.



Staff by segment as of year-end Full-time-equivalents

At the end of 2008, Biotest AG had 18 apprentices completing their professional training as office administrators, chemical lab technicians and biology lab technicians. We also employed three trainees.

#### Organisation and working hours

In the year under review, we implemented new working time models in the Plasma Proteins segment in connection with the expanded manufacturing periods. In the areas of intermediates and plasma fractionation, the continuous alternate shift work model was adopted in March and at the end of May 2008 respectively. This means that the facilities operate around the clock seven days a week. Arrangements regarding working hours and bonuses were made with the involvement of the employee council.

For all other production steps, we have also introduced flexible arrangements in cooperation with the employee council, which meet the requirements of continuous operation.

The staff transfer from Production, Automation Equipment, Sales and Marketing and Quality Management within the Medical Diagnostic segment to Biotest Medical Diagnostics GmbH was completed according to schedule as part of the transfer of undertakings on 1 January 2008. Like Biotest AG, the company is a member of the Association of Employers in the Chemical Industry and it took over all existing company agreements.

A socially responsible solution was developed for the necessary reduction by 44 jobs. Approximately half of the employees concerned changed to jobs within the Biotest Group.

Cooperation with the employee council of Biotest Medical Diagnostics GmbH and the new Biotest Group employee council, set up following the establishment of the subsidiary, has been good from the start.

#### Remuneration

Variable remuneration for members of the sales team in Germany in the Plasma Proteins segment was restructured in the reporting year. The selected model facilitates more targeted sales management, for example.

In May 2008, the third tranche of the Long Term Incentive Programme (LTIP) was launched. This system regulates performance-related pay of specialist and management staff at Biotest. The tranche runs from 2008 to 2010 and disbursement of the incentive payment is scheduled for 2011. The LTIP agreement also encompasses employees at subsidiaries and affiliated companies abroad. However, in the USA, the conditions for participation are not linked to a personal investment by employees. Details on the structure and participation criteria are provided in the notes to the consolidated financial statements.

We implemented new working time models in the Plasma Proteins segment.

#### Personnel development

#### Executive and trainee executive development

Biotest has considerably stepped up its activities in this area. In April 2008, the Effective Management & Leadership programme was launched, which promotes the development of promising staff members in the company. The programme applies to employees at all management levels and comprises six modules relating to the topics of management, leadership and personal development. In addition, participants discuss current topics for their respective field of activity as part of an Action Learning session and develop solutions together.

With a view to adopting an international approach to executive development, the programme was also launched for employees from affiliated companies in November 2008.

In 2008, three participants started their training under the new trainee programme with a focus on sales and marketing. The programme targets science and business studies graduates and runs for two years. During this period, it is mandatory for trainees to work abroad for a six-month period.

In cooperation with a firm of consultants, we launched a 360 degree feedback programme in the fourth quarter of 2008. Participants, initially members of the senior management team, receive feedback on how their leadership is perceived by superiors, colleagues and their own team of employees. The results provide the basis for staff development measures tailored to each individual.

#### Training and continuous professional development

Biotest created the conditions for additionally offering training for electronic plant technicians and industrial engineers at the Dreieich site from the start of the new training year (August 2009). Moreover, the total number of training places offered by the company will be doubled.

For fully qualified technical employees Biotest has introduced a new option for further professional qualifications with the vocational training course for German training qualification "Industriemeister Chemie" (industry master in chemistry). The first participants will be starting the course in financial year 2009.

### Supplementary report

In January 2009, Biotest was granted approval for its albumin preparations Albiomin 5% and Albiomin 20% in six additional European core markets as part of the MR procedure. In February 2009, BPC acquired a plasmapheresis centre in Santa Fe, in the US state of New Mexico. The new facility is equipped to supply up to 40,000 litres of plasma per year. Consequently, the number of plasma collection centres operated by Biotest worldwide rose to 21.

Biotest has considerably stepped up its activities in personnel development.

The first participants started the new trainee programme.

The number of plasma collection centres operated by Biotest rose to 21.

# Risk and opportunities report

Business operations and the development of sales and results of Biotest to some extent depend on factors, the occurrence of which cannot always be predicted and which may be completely or partially beyond our control. This produces risks, which, should they arise, may have an adverse effect on Biotest's asset, financial and earnings position. At the same time, this situation offers the chance of stronger growth in business and earnings than described in the outlook report.

Since the collapse of US investment bank Lehman Brothers and the subsequent dislocations in the financial markets, the global economy has been subject to considerable uncertainty. At the time of writing this annual report, we believe that it was impossible to provide a reliable forecast of the extent and duration of the crisis in the financial system and the real economy. Where individual risk positions have changed as a result of the financial market crisis, these are described accordingly in the following paragraphs.

In close cooperation with the members of the senior management, the Board of Management continually obtains information about the current situation and is in a position to respond swiftly to any changes in the risk position of the company.

#### **Risk strategy**

The Board of Management and the Supervisory Board of Biotest have specified in their joint risk strategy report that the company may take controlled risks in cases where prospects exist for long-lasting profitable growth. As a matter of principle, all major Biotest managerial decisions, such as the approval of capital expenditure, are taken only after detailed assessment of the associated risks and opportunities.

This applies, in particular, to the development of monoclonal antibodies in the Biotherapeutics segment. The expenses already incurred and yet to arise for pre-clinical and clinical development, are considerable. Despite the consistently encouraging results to date, there is no guarantee that any of the three monoclonal antibodies will be approved. However, should approval be achieved, this will be associated with substantial additional sales and earnings potential for Biotest.

On the basis of milestone planning, we are consequently monitoring project progress on a continuous basis and beyond this, we regularly compare our estimates of the available potential with current market data.

#### **Risk management and controlling**

Biotest systematically compiles and assesses the operating and strategic risks. Their management forms an integral component of the overall management of the Group. All risks with wide-ranging implications and a reasonable probability factor are closely monitored.

Our IT-based risk management system fulfils the requirements of the German Corporate Sector Supervision and Transparency Act (Gesetz zur Kontrolle und Transparenz im Unternehmensbereich, KonTraG).

Major potential risks are an element of the monthly internal reporting system and beyond this, a risk management committee analyses the current exposure to risks in all segments and provides the Board of Management with a detailed risk report every six months.

Biotest has taken out insurance policies to limit the financial consequences of liability risks and material damage to plant and machinery. The scope of the protection afforded by insurance is regularly reviewed and adjusted where necessary.

Purchasing of financial derivatives to minimise interest rate and foreign exchange risks is carried out in line with the defined risk limits.

#### Presentation of significant individual risks

The risks described below are not the only such factors to which Biotest is exposed. Other risks and uncertainties, of which we may currently be unaware which we presently regard as insignificant, could impact on Biotest business operations and have an adverse effect on the asset, financial and earnings position of the company.

The order in which the risks below are listed is not in any way indicative of the probability of their occurrence.

#### **Economic risks**

The development of the overall economy has no or only a minor immediate bearing on the business situation of Biotest. The indirect effects are of greater significance, as the financial position of those playing a role in the healthcare sector and of public sector budgets depends on the development of the economy as a whole. Biotest could not remain permanently immune to the consequences of an extensive and lasting recession.

The risk of a possible downturn in sales is caused by potentially lower demand and/ or rising pressure from customers to reduce prices. Another potentially dampening effect results from the fact that Biotest may be forced to reduce or discontinue supplies to individual markets. This could be the case, if it were not possible to hedge sufficiently against default on the relevant accounts receivable, or if this would only be achievable at significantly worse terms and conditions. Even if the macroeconomic situation of a country deteriorated to the extent that serious impact on the healthcare system of that country could be expected, Biotest would be in a position to discontinue deliveries to such a country in order to minimise risk.

In view of the current economic environment, we believe that there are increased economic risks.

#### Supply market risks

We consider supply market risks to be the danger of shortages or price increases in the raw materials, auxiliary materials and operating supplies needed for production or in the products acquired through toll manufacturing.

Of particular importance is the supply of human plasma. Should donor willingness decline or new regulatory requirements on procurement come into effect, it could become more difficult to obtain the supplies of raw material needed.

In all operating segments, our production requires special raw materials, such as supplies of antigens, serums and biological products. Should a shortage or significant increase in the price of auxiliary and operating supplies occur, there is the risk that Biotest might be restricted in its production and supply capacity.

Biotest has concluded long-term agreements for the supply of raw materials for its production. This applies especially to the supply of blood plasma, a rising proportion of which we are also ensuring via our own plasmapheresis stations. The target quota for our own supplies is approximately 50%, which will ensure sufficient independence from price fluctuations in the global market.

We are therefore of the opinion that the supply market risk is very limited.

#### Supply relationship risks

Biotest buys preliminary and intermediate products from external suppliers. This involves the risk that individual business or cooperation partners may not comply with, or may not comply adequately with, their obligations or may terminate existing agreements. There is also a risk of claims against us for possible infringements committed by our partners.

Given that, as a rule, business relationships last many years and the close dialogue maintained with our suppliers, we believe that the probability of the relevant risks actually occurring is very low.

#### Risks relating to plasma as a raw material

Blood plasma is obtained from the blood or plasma of many donors. There is a residual risk of plasma contaminated with bacteria, viruses or prions that are currently known, but have remained undiscovered or were previously unknown, entering the production cycle. This could result in contamination of the end products.

Possible consequences would be the authorities mandating the recall of individual batches from the market, or restricting or suspending approval. In addition, contamination caused by previously unknown bacteria, viruses or prions could result in tighter legislative controls on plasma-based drugs.

Biotest applies the highest safety standards to obtaining and processing plasma, which in many aspects exceed the stringent legal standards. For example, when selecting the location of plasmapheresis centres, we exclude regions or districts of cities that are associated with a higher risk of infection from the outset.

All blood and plasma donations obtained are subjected to extensive testing and quarantine phases. The testing procedures we use comply with the latest scientific standards and reliably detect currently known bacteria and viruses. Biotest's manufacturing processes incorporate a number of viral deactivation or viral depletion stages, which further minimise the risk of contamination of the end products.

Contamination of end products is largely considered as excluded at present.

#### Process and production risks

Process and production risks are considered to be the impairment of an efficient and environmentally friendly provision of output through inefficient structures or production processes, or material damage to plant and machinery.

We are constantly monitoring and analysing our production processes in order to take swift action to deal with any possible risks arising at an early stage.

We do not currently see increased risk in this area.

#### Sales market risks

Sales market risks comprise risks associated with price, quantity, substitution and payment default.

In view of the expansion of capacity on a large scale in the pharmaceutical industry in recent years, the risk of a sudden price collapse for Plasma Proteins has increased compared with the situation in previous years. However, demand for these products continues to rise and this limits the risk. We monitor market developments very closely.

The development of further international markets and the conclusion of long-term supply agreements have enabled us to reduce the risk generated by short-term fluctuations in the volume of Plasma Proteins sold. However, the risk remains, in particular with regard to individual tenders, that the volume sold is lower than planned.

As Biotest Plasma Proteins are complementary products, there is a risk that different sales opportunities for the individual end products could lead to increased stocks of other primary and end products.

Substitution risks exist primarily for plasmatic coagulation preparations in industrialised countries. Other countries switching to recombinant factors could adversely affect Biotest's sales opportunities there. According to our observations, the relationship of the plasmatic and recombinant factors used worldwide remains stable. We see no trends that suggest a change in this correlation in the short term. The risk of default on trade receivables has significantly increased as a result of the impact of the financial market crisis on the ability to pay of companies and governments in some regions. Biotest observes developments in trade receivables and, where necessary, limits the associated risk. In addition to factoring and taking out insurance policies, another option is to limit the business volume in regions which have been identified as high-risk.

#### Side effect or drug interaction risks

In drugs which have already received approval, unexpectedly severe or previously unknown side effects or drug interactions may arise. Inappropriate handling, storage or application of our preparations can also give rise to considerably negative effects on recipients and patients.

Measures that the authorities need to take in such cases range from ordering a recall of single batches to the restriction or suspension of approval. Side effects, drug interaction or inadequate quality may also have an adverse effect on the reputation of Biotest.

Close dialogue with hospitals and the relevant specialist doctors' surgeries enables us to ensure that we are made aware at an early stage of any new side effects and drug interactions that become known.

#### Research and development risks

Many clinical tests are necessary on new drugs prior to approval and market launch and there is a risk that the therapeutic effects of the treatment, which had previously been assumed to exist, are not confirmed. In addition, it is impossible to put a precise figure on the level of investment in development required in advance, since unforeseen additional costs may arise.

This is a risk which is particularly relevant to the early research phases of monoclonal antibodies. Since this involves entering new pharmaceutical-technical terrain, there is an increased risk that developments fail either in part or completely, that approvals are not granted as anticipated, or that third parties initiate patent infringement proceedings.

On the basis of milestone planning, we constantly monitor the developmental progress of individual projects. We carry out regular interim analysis to evaluate the data obtained in pre-clinical and clinical development, in order to create a reliable decision-making basis on how to proceed with the project. Under the terms of our patent strategy, we continually verify and extend the patents protecting our products.

#### Personnel risks

Personnel risks arise from the potentially deliberate or accidental misconduct of employees, which might negatively affect production efficiency or safety.

Other risks include the fact that Biotest may not be in a position to retain employees in key positions or be able to find suitable candidates for such positions. This applies in particular in view of the prevailing, or clearly emerging, lack of specialist staff, which is due in part to demographic developments. In addition, the high density of pharmaceutical and chemical companies in the Rhine-Main region has resulted in fierce and increasing competition for high-performing employees and talent.

Biotest takes action to avoid personnel risks through ongoing and targeted employee training, attractive training programmes and a performance-related remuneration scheme for management. The company's growth and internationalisation have considerably enhanced the attractiveness of the Group as an employer.

#### Economic and currency risks

Biotest earns part of its sales in foreign currencies. Exchange rate fluctuations in the rate between the euro and these currencies could impact on the Group result as well as on the sales potential in individual markets. In recent weeks, in particular, the currencies of UK, Hungary, Turkey, Poland and Russia have lost much of their value. Although sales of our products in these countries, which are invoiced in the local currencies, are stable, the relevant sales figures have decreased significantly when translated into euros. It is not possible to absorb such losses in value in full, using derivative financial instruments.

The profit contribution of Biotest Pharmaceuticals Corp. (whose activities are processed in US dollars) to the Group result (which is calculated in euros) depends in part on the exchange rate between the two currencies. Biotest uses derivative financial instruments to hedge the currency risk.

Economic risks may arise from the unexpected calling in of credit lines or a sudden increase in the lending rate. Following the impact of the financial market crisis on banks worldwide, the risk has increased in particular that credit lines which are coming to an end cannot be extended, or can only be extended at considerably less favourable terms and conditions.

Biotest has concluded long-term agreements for a major proportion of debt financing. There is also long-term financing for some current assets. We consider the overall ratio between equity and liabilities to be balanced. Biotest maintains an ongoing dialogue with the lending banks. The greatest share of the credit line is made available by Commerzbank AG, which has utilised the guarantees and equity assistance of the special fund for stabilising the financial markets. From the point of view of the Board of Management, the overall risk arising from financial and economic factors is still manageable. However, compared with previous years, this risk needs to be monitored carefully. With regard to potential financing risks in the event of the majority shareholder of Biotest AG changing (change of control), we refer to the explanations provided at the end of the Group management report regarding information pursuant to Section 315 (4) of the German Commercial Code (HGB).

#### **Political risks**

A proportion of Biotest sales generated by the Plasma Proteins segment is attributable to tender business. In certain countries, business of this type is subject to a high level of political influence, a situation which might lead to a contract granted to Biotest being revoked. In such cases, even if Biotest has already invested in the tender, there is a very limited chance of compensation and this is only awarded if the company invests considerable efforts to make a claim. As Biotest acts with a high level of risk awareness in this market sector, the associated risk can be regarded as minor.

Biotest maintains relations with companies worldwide. In unfavourable circumstances, any destabilisation of the political situation in individual countries could adversely affect business relations and prospects. If international sanctions are imposed against Iran, this may jeopardise the goals of the BioDarou joint venture.

In some Eastern European countries and parts of South America, a deterioration in the economic situation may also result in higher instability of local political systems, as a result of which limits may be introduced on currency amounts exported as well as import and export restrictions implemented. This also represents a risk in terms of the business relations of Biotest with such countries, which are usually maintained via government organisations.

#### Other risks

The tax statements of Biotest AG for the years 2004 to 2008 remain subject to audit by the tax authorities. Further demands established in the tax audit for the period from 1999 to 2003, for which the relevant tax bill has yet to be received, are covered in the annual financial statements.

Preliminary proceedings are pending against Biotest AG and Biotest Pharma GmbH for alleged violation of the Foreign Trade Law in connection with the United Nations "Oil for Food" programme introduced for Iraq. The case could have grave consequences for the parties responsible, including custodial sentences. The company considers the claims to be unfounded and does not therefore believe that the proceedings represent an increased risk.

As of the balance sheet date, Biotest still had tax loss carryforwards. In the event of more than 25% of the shares in Biotest AG with voting rights being sold, it would no longer be possible to realise these at all, or only in part.

#### **Opportunities**

Biotest practises a comprehensive corporate management approach to opportunities and risks. Continuous monitoring of sales markets and regulatory framework conditions enables us to identify associated opportunities at an early stage.

Close and constant dialogue with leading physicians also keeps us informed of the current status of medical developments in the markets relevant to us and we record scientific publications on the medical fields that are significant to Biotest in an inhouse database. This enables us to identify further potential areas of indications for our Plasma Proteins.

From the current perspective, the most interesting opportunities can be summarised as follows:

- In the Plasma Proteins segment, the possibility exists that new medical findings will significantly increase the indication spectrum of Biotest's preparations. The same applies to the development candidates of the Biotherapeutics segment.
- For Biotest Medical Diagnostics GmbH, the critical size achieved by entering into partnership with another company could generate synergetic potential.

#### General statement on the risk situation of the Group

It is the opinion of the Board of Management that Biotest is not currently subject to any risks extending beyond those which are an inevitable part of its business operations. All material risks are constantly monitored and where possible and reasonable, precautions are taken accordingly to avoid any potential financial consequences arising.

No risks are currently evident which might jeopardise the financial stability of the Biotest Group.

## Outlook

#### Statements relating to future expectations

The expectations and forecasts of the Board of Management regarding the future business development of the Biotest Group are based on assumptions made on the most probable scenario from the current perspective. However, it should be said that like all predictions of future development, these are associated with a degree of uncertainty. The actual development of the market environment in Biotest segments may differ considerably from the assumed development, both in a positive and negative direction.

#### Strategic direction of the Group in financial years 2009 and 2010

Biotest intends to continue the internationalisation of the company and its business, which is defined by its corporate strategy, in the current and next financial year. The focus will be on expanding the company's position in its European core markets and the USA. Research and development of new products and the targeted enhancement of products which have already been launched in the market represent an ongoing task for a quality provider such as Biotest.

Cooperation with partner companies will play a more important role given progress made with the various projects, in particular in the Biotherapeutics segment. We expect to sign an agreement with one of the companies from the circle of the "Big Pharmaceuticals" in the current year, the object of which is the joint further development of the BT-061 monoclonal antibody.

The continued internationalisation of the company and its business is reflected in the expansion of personnel management structures. Existing and new concepts for staff development and participation will progressively be expanded to include Group companies abroad, especially in the USA.

In 2009, Biotest will be extending its remuneration system for pay-scale employees in Germany to include an additional retirement provisioning component. This involves crediting a specific amount as part of profit sharing to an account under the new Biotest provisioning savings scheme on their behalf. All other employees may also participate in this savings scheme by converting a portion of their gross salary and paying it into a company pension plan on a voluntary basis. This procedure is associated with benefits in terms of tax and social security for all participating employees.

#### **Development of market conditions**

#### **Overall economy**

All forecasts predict a dramatic decrease in economic activity in almost all global regions. However, individual assessments vary substantially in terms of the extent and duration of the economic crisis and all are subject to a high level of uncertainty.

The International Monetary Fund expects growth in global economic output of 0.5% in the coming year, the weakest since 1991.

For Germany, the German government expects a downturn in GDP of 2.25% while the EU Commission forecast of January 2009 for the 27 European Union member states indicated a decline in GDP of 1.8%. The International Monetary Fund has forecast a decrease in GDP of 1.6% for the United States of America.

We base our statements regarding economic development of the Biotest Group on the expectation that the markets which are relevant to our business will see moderate growth in the current year. Since many of the drugs and diagnostic equipment produced by Biotest are life-saving and/or necessary to meet regulatory requirements, demand for these goods is largely independent of economic growth.

The main risk is that financing of the treatments, some of which are very cost-intensive, may be affected by the consequences of the crisis. The losses in assets resulting from the financial crisis and, in particular, the expenses associated with the measures implemented to stabilise the financial system and economy will impact heavily on public budgets for the coming years. Coupled with the consequences of the economic downturn, it is highly likely that this will increase pressure on institutions financing the healthcare systems in all Biotest's major sales markets. Accordingly, further costcutting measures can be expected. However, no health policy measures which would impact directly on sales opportunities for our products are yet discernible.

#### **Plasma Proteins**

According to our estimates, the demand for immunoglobulins and other Plasma Proteins will continue to rise with an annual growth rate of between 6% and 8%. Growth will therefore be somewhat more moderate than in it was in the previous years. The key driver of this demand is the ongoing expansion of the indication spectrum for Plasma Proteins. With regard to coagulation factors, there is also scope for market growth given the low treatment quota with only around a quarter of haemophiliacs receiving prophylactic treatment.

In recent years, manufacturers have considerably expanded their capacities for obtaining plasma and many of the new plasmapheresis centres opened will only be producing to full capacity in the current year. Our assumption is that this will result in surplus demand in the global market being reduced in full in the course of this year. Consequently, the upward trend in prices will slow down somewhat and for some products and markets, such as albumin, a decrease in prices can be expected.

Tenders relating to high-volume deliveries to emerging countries will continue to offer attractive business opportunities for providers. However, in view of the expected greater availability of plasma and the general recession in the global economy, we initially expect a noticeable decrease in prices during the current year.

#### **Microbiological Monitoring**

The sector economy of the pharmaceutical industry will not be able to decouple completely from the negative trend in the overall economy. In principle, the pharmaceutical sector is one of the economic sectors which is less susceptible to fluctuations. Since hygiene monitoring of air and surface conditions is subject to stringent official standards, companies cannot simply dispense with it. However, a lower volume manufactured will also result in less demand for the relevant products. According to our assessment, the pressure to achieve cost savings will prompt pharmaceutical companies to look for further options and make processes more efficient and less cost-intensive. This should impact favourably on demand for integrated systems, such as those included in the range of products of Biotest HYCON and heipha Dr. Müller GmbH.

#### **Medical Diagnostics**

Our forecasts are based on the assumption that the difficult market conditions for providers of transfusion, transplantation and infection diagnostics in Europe will hardly change in the current and next year. In the USA, the economic crisis will also affect the sector economy. Since there is no indication of further market entries by new providers, the market will still remain attractive.

#### Expected sales and earnings growth at the Biotest Group

Detailled statements cannot be made from today's perspective as to whether and to what extent the anticipated recession in the core sales markets will affect sales and earnings of the Biotest Group.

In line with the strategic perspective already defined in previous years, the Board of Management still expects sales growth of some 10% for 2009 and 2010 respectively. With regard to income, the Board of Management anticipates that Biotest will maintain the same level of operating profit (EBIT) achieved in the financial year ended.

#### **Expected segment developments**

#### **Plasma Proteins segment**

We expect the European approval authorities to confirm acceptance of the second chromatography facility for the production of immunoglobulins by the end of March 2009. Following approval, Biotest will have access to annual production capacity of four tonnes of immunoglobulins in Dreieich (instead of the previous two tonnes). Sales of products manufactured in the new plant will commence immediately after approval.

The new plasma fractionation facility in Boca Raton is scheduled for completion at the end of 2009. At the same time, we expect the clinical trial for the immunoglobulin to be concluded. The documentation on the new facility and the results of the clinical trial will then be submitted for approval to the FDA, the US health authority.

We expect commissioning of the facility in Boca Raton by the regional board in Darmstadt as early as the autumn. As soon as approval has been granted by the authority, Biotest will be able to process the intermediate products manufactured in the USA as part of Plasma Proteins manufacturing into end products at its Dreieich plant. We will subsequently submit these to the relevant state authorities for approval. In the current and next year, Biotest will open further plasmapheresis centres in Europe and the USA to cover the growing raw material requirements resulting from the expansion of capacity. In addition, we also intend to take further steps towards achieving our strategic goal of obtaining approximately 50% of the blood plasma processed by Biotest in the company's own centres.

With regard to the Plasma Proteins under development and already approved, the following stages are scheduled in the current and next year.

**IgM concentrate:** The clinical Phase I trial is scheduled for completion by year-end 2009.

**IVIG:** The final report on the clinical Phase III trial, which forms the basis for the application for approval by the FDA, should be available by the end of 2009. Approval is expected at the end of 2010.

**Zutectra®:** The central European approval procedure for the variant of the Hepatect<sup>®</sup> hyperimmunoglobulin for subcutaneous administration (injection below the skin) is scheduled for completion by the end of 2009.

**Intratect**<sup>®</sup> (in the indication of fibromyalgia): The final report on the clinical Phase III trial is expected to be available to Biotest by the end of the first six months of 2009.

**Nabi HB®:** We are currently examining whether Biotest would benefit from seeking approval for the preparation in markets outside the USA.

#### **Microbiological Monitoring**

From a series of new and enhanced developments, which we plan to bring to market in 2009 and 2010, the integration of the HYCON ID and heipha data matrix code systems into a single laboratory software version stands out. Scheduled for the first half of the current year, its introduction represents a significant step forwards in the move to achieve the paperless laboratory. We expect to gain the first customers for the new system from among the circle of major pharmaceutical companies before the end of this year.

#### **Medical Diagnostics**

In Medical Diagnostics, our target is to report positive operating profit again in 2009. The decisive factors will be the significantly more favourable cost structure and increasing sales in high-margin business in the USA.

In Research and Development, we intend to start assessing potential further developments of the TANGO<sup>®</sup> optimo system. Furthermore, we intend to progress development work on a new HLA/DNA platform as well as a procedure for molecular blood group typing, which is primarily aimed for distribution in the US market.

#### **Biotherapeutics**

We shall continue to give priority to advancing the development projects for monoclonal antibodies. We expect to complete work on setting up GMP-compliant production of monoclonal antibodies at our Boca Raton plant in the current year and to be in a position to already start manufacturing first batches.

With regard to BT-061, we will conclude the clinical Phase I/IIa trials in the indications of psoriasis and rheumatoid arthritis in 2009. The clinical Phase II trial in the indication of rheumatoid arthritis, in which BT-061 is administered in combination with the current standard treatment with methotrexate, is also scheduled for completion in the current year. Further clinical Phase II trials will start for both indications.

We will continue to proceed with negotiations already underway with potential partners for the development and marketing of BT-061. We anticipate that the cooperation agreement will be signed at the end of 2009. In parallel with the advancing development processes, we will examine additional indications for which BT-061 can be developed further.

With regard to BT-062, we intend to start recruiting patients in the current year for further clinical Phase II trials in the indication of multiple myeloma. We also plan to launch a pre-clinical trial on the efficacy of the antibody in treating solid tumours.

Moreover, 2009 will see the start of clinical testing of BT-063.

# Details in accordance with Section 315 (4) of the German Commercial Code (HGB)

The subscribed capital of Biotest AG in accordance with the Articles of Association amounts to €30.03 million. It is divided into 6,595,242 ordinary shares and 5,133,333 preference shares. The shares are bearer shares; preference shares do not carry voting rights.

On 12 February 2008, OGEL GmbH notified us that it holds 50.03% of the ordinary share capital of Biotest AG. The company is under the control of Dr. Cathrin Schleussner, who is a member of the Supervisory Board of Biotest AG. The Kreissparkasse Biberach has notified us that it held 24.36% of the shares carrying voting rights as of 20 January 2007.

Beyond this, the Board of Management is not aware of any direct or indirect shareholdings in the company exceeding 10% of the voting rights. There are no shareholders with special rights conferring controlling rights. The members of the Board of Management are appointed and removed by the Supervisory Board, in accordance with the provisions of Sections 84 and 85 of the German Stock Corporation Act (AktG) and Article 7 (2) of the Articles of Association. Pursuant to Section 179 (1) of the German Stock Corporation Act (AktG), all amendments to the Articles of Association require a resolution to be passed by the Shareholders' Meeting (Section 133 AktG). The authority to amend the version of the Articles of Association has been assigned to the Supervisory Board according to Article 27 of the Articles of Association in compliance with Section 179 (1) Clause 2 of the German Stock Corporation Act (AktG).

In accordance with the resolutions adopted by the Shareholders' Meeting on 27 May 2008, the company is authorised to acquire its own shares pursuant to Section 71 (1) Clause 8 of the German Stock Corporation Act (AktG) up to a value of 10% of the share capital of € 30,025,152 existing at the time of the Shareholders' Meeting. Together with other own shares held by the company or own shares that are attributable to it pursuant to Sections 71 aff. of the German Stock Corporation Act (AktG), the shares acquired must at no time amount to more than 10% of the share capital.

The authorisation is valid until 26 November 2009; the company has not exercised its rights under this authorisation to date. An authorisation to acquire own shares adopted by the Shareholder's meeting on 3 May 2007 was repealed.

Furthermore, the resolution adopted by the Shareholders' Meeting on 20 May 2005 authorised the Board of Management to increase the company's share capital by up to €10,240 thousand by 19 May 2010 with the approval of the Supervisory Board, by issuing new ordinary and/or new preference shares against cash contributions and/ or contributions in kind.

Following the capital increases of 3 August 2005, 18 October 2005 and 28 September 2007, authorised capital amounts to €695 thousand.

The resolution adopted by the Shareholders' Meeting on 8 July 2004 authorised the Board of Management to issue profit participation rights with a nominal amount of up to €50,000 thousand until 7 July 2009 with the approval of the Supervisory Board. In financial year 2005, usage was made of this authorisation in the amount of €10,000 thousand. On 25 November 2005, the company entered into a participation rights agreement with a term of seven years and a total volume of €10,000 thousand. This amount was paid on 5 December 2005 with a discount of 3.4%. The loan is a subordinated bullet loan and the interest is comprised of a variable and a fixed component. The variable component is dependent on financial indicators of the company.

Biotest AG has concluded significant agreements with third parties in respect of the long-term financing arrangements of the Group which take effect in the event of a change of control. The syndicated loan agreement grants the lending banks the right to terminate the agreement in the event of a change of control at Biotest AG or Biotest Pharmaceuticals, where they consider that this would make the continuance of the agreement unacceptable. The participation rights agreement relating to a loan agreement falling due at maturity at a nominal value of  $\leq 10.0$  million provides for the possibility of extraordinary termination rights for creditors. In the event of termination, the entire sum would fal immediately due, and compensation for premature termination would additionally be payable.

The service agreements of both members of the Board of Management include a provision governing settlement in the event that the Board of Management agreement is prematurely terminated as a result of circumstances defined in detail as a change of control. Settlement comprises the fixed remuneration to the end of the contractual term plus any bonuses which may be due pro rata for the period concerned, calculated on the average amount of the past two financial years, plus a consideration taking into account the use of a company car.

If the remaining period is less than three years, the settlement shall constitute three times the annual fixed remuneration, plus bonuses and consideration for the company car. There shall be no entitlement if the Board of Management contract is terminated for serious reasons, illness or incapacity to work, or if members of the Board of Management have reached the age of 60 respective 62 at the time of termination or have received considerations or benefits from a third party in connection with the change of control.

# **Income Statement**

of the Biotest Group for the period from 1 January to 31 December 2008

€ thousand	Note	2008	2007
Revenue	D1	422,956	326,419
Cost of sales		- 203,819	- 153,840
Gross profit		219,137	172,579
Other operating income	D5	6,889	6,533
Distribution expense		- 81,002	- 72,104
Administrative expense		- 40,216	- 25,960
Research and development expense	D4	- 43,676	- 34,476
Other operating expenses	D6	- 5,493	- 6,572
Operating profit Biotest Pharmaceuticals Corporation	D12	-	- 1,488
Operating profit		55,639	38,512
Financial income	D7	3,934	1,177
Financial expenses	D8	- 19,041	- 9,349
Financial result		- 15,107	- 8,172
Costs relating to associated companies	D9	-	-184
Profit before tax		40,532	30,156
Income tax	D10	- 12,413	- 12,879
Profit after tax		28,119	17,277
thereof:	_		
Retained earnings attributable to equity holders of the parent company		25,742	15,522
Minority interest		2,377	1,755
Earnings per share in €	E11	2.17	1.39
Additional dividend right per preference share in €	E11	0.06	0.06
Earnings per preference share in €	E11	2.23	1.45

The notes are an integrated part of the consolidated financial statements.

# **Balance sheet**

of the Biotest Group as of 31 December 2008

€ thousand	Note	31 December 2008	31 December 2007
ASSETS			
Intangible assets	El	73,808	73,356
Property, plant and equipment	E2	209,786	191,764
Finance lease assets	E2	20,109	22,431
Investments in affiliates	E3	100	155
Other financial assets	E5	237	258
Trade receivables	E8	451	_
Other assets	E9	2,072	975
Deferred tax assets	E6	5,990	5,871
Total non-current assets		312,553	294,810
Inventories	E7	156,554	116,871
Trade receivables	E8	94,030	101,141
Current income tax assets		2,442	1,226
Other assets	E9	18,393	13,765
Cash and cash equivalents	E10	8,072	8,889
Total current assets		279,491	241,892
TOTAL ASSETS		592,044	536,702
EQUITY AND LIABILITIES		30,025	20.025
Subscribed capital			30,025
Share premium		153,332	153,332
Reserves		39,826	23,614
Retained earnings attributable to equity holders of the parent company		25,742	15,522
Shareholders' equity	E11	248,925	222,493
Minority interest		4,449	3,267
Total equity	E11	253,374	225,760
Provisions for pensions and similar obligations	E12	43,388	43,103
Other provisions	E13	3,653	2,645
Financial liabilities	E14	166,648	162,690
Other liabilities	E15	220	_
Deferred tax liabilities	E6	6,416	3,780
Total non-current liabilities		220,325	212,218
Other provisions	E13	19,270	16,787
Current income tax liabilities	115	4,679	6,796
Financial liabilities	E14		
	E14	28,192	26,069
Trade payables	F1F	48,730	32,117
Other liabilities	E15	17,474	16,955
Current liabilities Total liabilities		118,345	98,724
iotal habilities		338,670	310,942

The notes are an integrated part of the consolidated financial statements.

# Statement of recognised income and expenses of the Biotest Group for the period from 1 January to 31 December 2008

€ thousand	2008	2007
Differences from currency translation	3,443	- 483
Costs of capital increase	-	- 465
Actuarial gains from defined benefit pension plans	1,756	1,319
Deferred tax on gains/losses recognised in equity	- 544	- 172
Other income/expenses recognised in equity	- 109	- 129
Gains/losses recognised in equity	4,546	70
Profit for the period	28,119	17,277
Total profit	32,665	17,347
thereof:		
Retained earnings attributable to equity holders of the parent company	30,280	15,564
Retained earnings attributable to minority interests	2,385	1,783
Total profit	32,665	17,347

# Cash flow statement

of the Biotest Group for the period from 1 January to 31 December 2008

€ thousand	Note	2008	2007
Profit before tax		40,532	30,156
Depreciation and amortisation of intangible assets and property, plant and equipment	E1; E2	26,232	16,367
Loss from associates		-	184
Amortisation of securities held as financial assets		_	1,008
Gains (2007: losses) from the disposal of assets		- 15	30
Decrease of pension provisions	E12	- 298	- 558
Financial result		15,107	8,172
Cash flow from operating activities before changes in working capital		81,558	55,359
Increase in other provisions	E13	3,315	4,895
Increase in inventories, accounts receivable and other assets		- 37,363	- 31,201
Increase in liabilities and other terms on the liabilities side		15,178	11,628
Cash flow from changes in working capital		- 18,870	- 14,678
Interest paid		- 14,440	- 5,657
Taxes paid		- 13,759	- 6,550
Cash inflow from operating activities		34,489	28,474
Cash from the disposal of fixed assets		192	290
Payments for the investment in fixed assets	E1; E2	- 36,539	- 32,186
Payments for the acquisition of additional shares		-	- 55
Payments for the acquisition of the Plasma Proteins business from Nabi Biopharmaceuticals		_	- 133,237
Changes in other financial assets		76	83
Interest received		3,199	609
Cash outflow from investing activities		- 33,072	- 164,496
Dividend payment for the previous year	E11	- 3,827	- 2,839
Dividend payments to minority interests	E11	- 1,162	-1,203
Proceeds from capital increase	E11	-	33,139
Payments for the costs of the capital increase		-	- 465
Proceeds from the inclusion of financial liabilities	E14	36,253	154,572
Payments for redemption of financial liabilities	E14	- 33,561	- 47,102
Cash outflow (2007: inflow) from financing activities		- 2,297	136,102
Cash changes in cash and cash equivalents		- 880	80
Exchange rate-related changes		63	- 94
Cash and cash equivalents at the beginning of the period	E10	8,889	8,903
Cash and cash equivalents at the end of the period	E10	8,072	8,889

The notes are an integrated part of the consolidated financial statements.

## A General

The Biotest Group comprises Biotest Aktiengesellschaft (Biotest AG), the parent company with registered office in Dreieich/Germany, as well as its subsidiaries in Germany and abroad. The Group's headquarters are located at Landsteinerstrasse 5, D-63303 Dreieich, Germany. Biotest is a pharmaceutical, biotherapeutic and diagnostic company active in research and production and specialises in immunological and haematological applications.

With effect from financial year 2008 the Biotest Group reports five segments. The previous Diagnostics segment was divided into the two segments Microbiological Monitoring and Medical Diagnostics. All figures from the financial year 2007 where adjusted accordingly. The segment previously known as Pharmaceuticals is now called Plasma Proteins, with its structure remained unchanged. The Biotherapeutics segment remained also unchanged. The Corporate segment is a non-operative segment.

In its Plasma Proteins segment, Biotest develops immunoglobulins, coagulation factors and albumins on the basis of human blood plasma, which are used for diseases of the immune system and the haemopoietic systems. The products are manufactured on the basis of blood plasma and human blood. Plasma Service Europe GmbH, Dreieich/Germany, Plasmadienst Tirol GmbH, Innsbruck/Austria, Plazmaszolgálat Kft., Budapest/Hungary, established in 2008 and Biotest Pharmaceuticals Corporation, Boca Raton/USA support the supply of blood plasma within the Group.

In addition, in its Biotherapeutics segment, Biotest promotes the clinical development of monoclonal antibodies, including for rheumatism and leukaemia indications.

The Medical Diagnostics segment encompasses products for blood group and tissue typing. Its range of products primarily comprises reagents, test serums and test systems.

The Microbiological Monitoring segment develops and markets products used in industrial hygiene monitoring. The products include test serums, culture media and hygiene monitoring devices.

The Biotest Group has 2,108 employees worldwide.

The consolidated financial statements of Biotest AG and its subsidiaries have been prepared in accordance with the International Financial Reporting Standards (IFRS), which are mandatory in the European Union. The IFRS comprise the International Financial Reporting Standards (IFRS) and the International Accounting Standards (IAS) as well as the interpretations of the International Financial Reporting Interpretation Committee (IFRIC) and the interpretations of the Standing Interpretation Committee (SIC). Accounting at the Biotest Group is based on the IFRS whose application is mandatory for financial years commencing on 1 January 2008.

In their present version, the consolidated financial statements comply with the provisions of Section 315a of the German Commercial Code (HGB). The provisions form the legal basis in Germany for consolidated accounting in accordance with international standards in conjunction with (EC) Regulation No. 1606/2002 by the European Parliament and Council dated 19 July 2002 regarding the application of international accounting standards.

Unless otherwise indicated, all amounts are stated in thousands of euros ( $\notin$  thousand).

On 27 February 2009, the Board of Management of Biotest AG authorised the consolidated financial statements for issue to the Supervisory Board.

#### Changes in accounting and valuation methods due to new standards

The accounting and valuation methods applied in the previous year have been retained. In addition, the Biotest Group has applied the following new or revised standards and interpretations, which are mandatory for financial years commencing on or after 1 January 2008.

The IAS 39 "Financial Instruments: Recognition and Measurement" and IFRS 7 "Financial Instruments: Disclosures" standards were amended in summer 2008 and their application is already mandatory for financial years commencing on or after 1 January 2008. The amendments relate to the reclassification of financial assets and do not affect the annual financial statements of the Biotest Group.

Furthermore, the Biotest Group has applied IFRS 8 "Operating Segments" instead of IAS 14 "Segment Reporting" since the start of financial year 2008, in line with the IASB recommendation. IFRS 8 requires companies to supply financial information and descriptions of their reportable segments. Operating segments which are subject to reporting requirements are components of a business that meet specific criteria. In this connection, separate financial information must be available for each segment, which must regularly be checked by the highest management body (chief operating decision maker), in order to assess business performance and decide how resources should be allocated. This segment structure is used for management purposes within the company.

#### Standards/interpretations not applied ahead of schedule

The IASB has issued and/or amended a series of additional accounting standards and interpretations whose application is mandatory from 1 January 2009 at the earliest, provided that they are passed by the Council of the European Commission and are relevant to the Biotest Group.

Standards/ Interpretations	Title	Application from
IAS 1	Presentation of Financial Statements (revision)	1 January 2009
IAS 1/IAS 32	Puttable Financial Instruments and Obligations Arising on Liquidation	1 January 2009
IAS 23	Borrowing Costs	1 January 2009
IAS 27/IFRS 1	Cost of an Investment in a subsidary, jointly- controlled entity or associate	1 January 2009
IAS 27	Consolidated and Separate Financial Statements	1 July 2009
IAS 39	Financial Instruments: Recognition and Measurement: Eligible Hedged Items	1 July 2009
IFRS 2	Share-based Payments: Vesting Conditions and Cancellations	1 January 2009
IFRS 3 revised	Business Combinations	1 July 2009
IFRIC 12	Service Concession Arrangements	1 January 2008*)
IFRIC 13	Customer Loyalty Programs	1 July 2008
IFRIC 15	Agreement for the Construction of Real Estate	1 January 2009
IFRIC 16	Hedges of a Net Investment in a Foreign Operation	1 October 2008

\*) IFRIC 12 are effective to financial years commencing on or after 01 January 2008. Since the European Union has not adopted this interpretation until today, its application is not mandatory.

From today's perspective, the first-time application of the accounting standards mentioned will have no material impact on the assets and liabilities, financial position and earnings of the Biotest Group.

# **B** Material accounting policies

# B1 Scope of consolidation

With 6 (2007: 5) domestic and 14 (2007: 13) foreign companies in which Biotest AG directly or indirectly holds the majority of voting rights, all material subsidiaries are included in Biotest AG's consolidated financial statements.

In financial year 2008, further changes were made to the scope of consolidation of the Biotest Group. The change in the scope of consolidation does not diminish comparability with the previous year.

With effect from 1 January 2008, Biotest AG transferred all activities relating to immunological diagnostics to Biotest Medical Diagnostics GmbH, which was established as a new wholly-owned subsidiary. Following restructuring in financial year 2007, this division was put in a position in terms of company law that enables it to enter into partnership with a potential strategic partner. This has created the basis for conducting a search for a strategic partner. Biotest Medical Diagnostics GmbH was included in the consolidated financial statements for the first time in financial year 2008.

In addition, the German company Plasma Service Europe GmbH established Plazmaszolgálat Kft., a new company in Budapest, Hungary, whose business purpose is the running of plasmapheresis centres.

In financial year 2007, Biotest AG had established the Biotest Pharmaceuticals Corporation in Boca Raton in the USA, which has absorbed the assets from the asset deal with Nabi Biopharmaceuticals. Another company, the Biotest US Corporation, Boca Raton/USA, was also set up in 2007 to benefit from potential tax advantages in the USA. This company holds all of the shares in the Biotest Pharmaceuticals Corporation.

As in the previous year, BioDarou P.J.S. Co. with registered office in Teheran/Iran is included in the consolidated financial statements as an associated company at equity.

The material companies included in the financial statements are listed in note F8 of the notes to the consolidated financial statements. Three subsidiaries without operating activities are not included in the scope of consolidation due to their negligibility. A complete listing of all companies in which an equity interest is held by the Biotest Group is disclosed in the online Federal Gazette (Bundesanzeiger).

# **B2** Consolidation principle

The reporting date for Biotest AG and all companies included in the financial statements is 31 December 2008. The financial statements of the companies included are prepared in accordance with uniform accounting and valuation policies prescribed by Biotest AG. Intragroup sales, expenses and income as well as accounts receivable and liabilities between the consolidated companies have been eliminated.

Capital consolidation is carried out pursuant to IFRS 3 according to the purchase method and the cost of purchase has been offset against the fair value of the equity attributable to the parent company at the time of purchase on a pro rata basis. Any remaining positive difference is recognised as goodwill in intangible assets. If the fair value of the pro rata equity capital attributable to the parent company is greater than the cost of purchase at the time of first consolidation, this results in a reassessment of the fair value. Any remaining amount in excess of the cost of purchase of the parent company is recognised immediately in the income statement. Goodwill is subject to regular impairment tests. Any lower fair values resulting from this measurement lead to unscheduled amortisation.

The first-time consolidation in the financial statements is effected at the time of acquisition.

According to IAS 28 "Investments in Associates", the amount carried for the investment should include other financial exposure (such as loans) as well as the cost of purchase.

Minority interests are the parts of the profit for the period and net assets of heipha Dr. Müller GmbH, Viro-Immun Labor-Diagnostika GmbH and Grundstücksverwaltungs GmbH, which relate to shares not held 100% by the Biotest Group. Minority interests are shown separately in the income statement and the balance sheet.

# **B3** Currency translation

The functional currency concept applies to the currency translation. The subsidiaries included in the Biotest Group conduct their operations independently and the functional currency of these companies is the respective local currency. When translating the annual financial statements of the subsidiaries whose functional currency is not the euro, assets and liabilities have been translated using the mean rate of exchange as of the balance sheet date and income and expenses have been translated using annual average rates. The resulting accumulated differences are recognised in a separate item in equity, which is reported under reserves in the balance sheet.

Under IAS 21 "The Effects of Changes in Foreign Exchange Rates", goodwill is translated as assets of the economically independent foreign subsidiaries at the rate as of the balance sheet date. The following exchange rates were applied for translating the currencies used by the fully consolidated companies of the Biotest Group:

	Average rates			es as of the nce sheet date
Equivalent of €1	2008	2007	31 Dec 2008	31 Dec 2007
US dollar	1.4706	1.3706	1.3917	1.4721
Pound sterling	0.7965	0.6846	0.9525	0.7334
Japanese yen	152.33	161.24	126.14	164.93
Swiss franc	1.5871	1.6427	1.4850	1.6547
Hungarian forint	251.74	251.32	266.70	253.73

Where monetary items (cash and cash equivalents, accounts receivable and liabilities) are recorded in local currency in the consolidated companies' individual balance sheets, these items are valued as of the balance sheet date. Resulting currency differences are reported under other operating income or expenses. Non-monetary items denominated in foreign currencies are carried at historical cost.

# B4 Intangible fixed assets

#### a) Goodwill

Goodwill arises on the acquisition of companies or shares in companies from the difference between the cost of purchase (purchase price) and the fair values of the acquired assets and liabilities. Goodwill is reported at the cost of purchase. Goodwill shown is tested at least annually for impairment and, if appropriate, amortised in accordance with IAS 36 "Impairment of assets".

As part of the impairment test, goodwill is allocated to the respective cash generating units. At the Biotest Group, the cash generating units correspond to the segments.

The allocable future cash flows of these cash generating units are used to determine their recoverable amount as the value in use on the basis of the discounted cash flow method. This method discounts cash flows based on the several-year business plan and a long-term growth rate forecast. The growth rate depends on the particular business and is between 0% and 2%. The after-tax discount rates of between 6% and 8% are based on the relevant weighted average cost of capital (WACC). Necessary writedowns are determined by comparing the book value of the cash generating unit with the recoverable amount.

#### b) Other intangible fixed assets

Other intangible fixed assets purchased are recorded at the cost of purchase and divided into assets with a definite or indefinite useful life. Assets with a definite useful life are amortised on a straight line basis over their estimated useful life. If necessary, unscheduled amortisation is recognised in accordance with IAS 36. The stated useful lives are between 3 and 10 years.

The amortisation period and the amortisation method for an intangible asset with a definite useful life are reviewed at least at the end of each financial year. If there is a change in the anticipated useful life of the asset or anticipated amortisation period of the asset, another amortisation period or amortisation method is to be selected. Such changes are treated as estimate changes. Amortisation on intangible assets with a definite useful life is reported in the income statement under the expense category which corresponds to the function of the intangible asset.

Intangible assets with an indefinite useful life are subject to an impairment test at least once a year at the level of the individual asset or at the level of the cash generating unit. There is no scheduled amortisation. The useful life of these intangible assets is to be reviewed at least once a year to check that the indefinite useful life is still justified. If this is not the case, amending the assessment from an indefinite useful life to a definite useful life is carried out on a prospective basis.

## B5 Property, plant and equipment

Property, plant and equipment are carried at cost of purchase and sales less accumulated scheduled depreciation and unscheduled depreciation in accordance with the purchase cost model. Depreciation is carried out on a straight line basis over the expected useful life in accordance with the component approach as follows:

Buildings	Up to 50 years
Machinery	5–12 years
Plant and equipment	3–10 years

If necessary, unscheduled depreciation is recognised in accordance with IAS 36. Here the book values of property, plant and equipment are compared with the respective recoverable amounts if there are any indications for impairment.

With regard to self-constructed property, plant and equipment, in addition to material and personnel costs, the conversion costs include an appropriate portion of overheads. Repair and maintenance expenses are recognised in the income statement when incurred. Extensions and material improvements are capitalised. Interest cost is recognised as an expense. Government grants reduce the cost of purchase or conversion.

#### **B6** Leasing

Whether or not an agreement is or contains a leasing relationship is determined on the basis of its economic content. Here an assessment is required as to whether the performance of the contractual agreement is dependent on the use of a specific asset or specific assets and whether the agreement grants the right to use the asset (IFRIC 4.6).

If assets are rented or leased and the Biotest Group essentially bears all the risks and rewards relating to the leased assets, such contracts are classified as finance leases. These are capitalised at the lower of the fair value and present value of the minimum lease payments at the time of contract conclusion in accordance with IAS 17 "Leases". Amortisation and depreciation are carried out over the expected useful life. Where necessary, unscheduled depreciation is recognised in accordance with IAS 36. The relevant payment obligations under the future lease payments are correspondingly recognised on the liabilities side of the balance sheet. The interest element of lease payments is recognised in the income statement as interest expense over the term of the lease agreement.

The assets capitalised in the context of finance leases mainly relate to production facilities and software.

Unless all the relevant risks and rewards related to the leased item transfer to the Biotest Group under lease agreements, the lease is accounted for by the lessor as an operating lease. The lease payments are recognised as expense when they are incurred.

#### **B7** Impairment

Should facts or circumstances imply the impairment of long-lived assets or an annual impairment test of an asset be required, the recoverable amount which represents the higher of the net sale value and its value in use is determined.

The recoverable amount is determined for each individual asset, unless the asset does not generate any cash flow that is largely independent of the cash flows of other assets or other groups of assets.

To determine the value in use, the estimated future cash flows are discounted to their present value, based on a discount rate before tax which reflects current market expectations relating to the interest rate effect and the specific risks of the asset.

If the recoverable amount is below the book value, the value of the asset is deemed to be impaired and it is written down to the recoverable amount.

Impairment expenses of the ongoing business divisions are recognised in the expense categories that correspond to the function of the impaired asset. In accordance with IAS 1, material amounts are shown as a separate line item in the income statement.

Apart from in relation to goodwill, write-ups to a maximum of the amortised cost are carried out if the estimated recoverable amount is higher than the book value.

#### **B8** Inventories

Inventories are carried at cost or at lower recoverable net selling value as of the balance sheet date. The latter corresponds to the estimated selling price which may be recovered in the course of the ordinary business, reduced by expected completion or selling costs. The conversion cost is determined on the basis of the "first in first out" method or weighted average. In addition to the directly allocable individual costs, pursuant to IAS 2 "Inventories", the production cost includes appropriate portions of the overheads locatable to the production process. These are based on the normal capacity of the production plant without taking account of interest costs.

#### B9 Trade receivables and other assets

Trade receivables and other assets are carried at nominal value. Accounts receivable denominated in foreign currencies are translated at the closing rates. Foreign exchange gains or losses are recognised as income or expenses. Default and transfer risks are accounted for through the recognition of allowances. The allowances are determined on the basis of experience and individual risk assessment. An allowance is recognised if there is an objective and substantial indication that the Group will not be in a position to collect the accounts receivable. Accounts receivable are taken off the books as soon as they become unrecoverable.

Accounts receivable which arise through application of the percentage of completion method are reported less payments on account if the cost of sale already incurred, including the profit portion, exceeds the payments on account received.

#### B10 Other financial assets

Financial assets are valued at fair value or cost of purchase at the time when they are first reported. With regard to all financial assets which are not subsequently valued at fair value and recognised in the income statement, the transaction costs attributable to the acquisition are taken into account. The fair values stated in the balance sheet generally correspond to the market prices of financial assets. Where these are not readily available, fair values are calculated using recognised valuation models and with reference to current market parameters. The cash flows determined already or established on the basis of forward rates using the current yield curve, are discounted by the discount factors specified on the basis of the yield curve applicable on the balance sheet date. The mean rates are applied.

#### B11 Cash and cash equivalents

Cash and cash equivalents comprise cash and current account balances, cheques and financial investments which can be disposed of at short notice with maturities of less than three months and are reported at their nominal value.

#### **B12** Pension provisions

The Biotest Group operates several defined contribution and defined benefit pension plans.

Commitments under defined contribution plans are determined by the contributions to be made in the period, so that in this case no actuarial assumptions are required.

Defined benefit plans are valued on the basis of actuarial opinions in accordance with the projected unit credit method. The pension costs for the financial year are forecast based on the approaches determined at the beginning of the financial year. The parameters included (interest rate, staff turnover rate, salary increases etc.) are anticipated factors.

Pursuant to IAS 19.93A – 19.93D all actuarial gains and losses are recognised directly in equity.

Any service period costs to be charged retrospectively, which arise in a financial year due to a retrospective change in pension commitments, are determined separately and amortised over the period until the claims are vested. If claims are already vested at the time of the change, the pension costs are recognised in the income statement as an expense in that period.

#### B13 Other provisions

In accordance with IAS 37, provisions are recognised when there is a present (legal or constructive) obligation arising out of a past event and it is probable that this will result in an outflow of resources to settle the obligation and a reliable estimate can be made of the outflow of resources. It is valued at the probable amount. Provisions with an expected completion time of more than 12 months after the balance sheet date are recorded at present value.

The provisions are discounted at a rate before tax that reflects the risks specific to the liability, whereby the increase in the provision caused by the passage of time is recognised as interest expense.

Material companies within the Biotest Group are subject to the collective wage agreements of the chemical industry and are consequently subject to the chemical industry's framework agreement on partial retirement for older workers. Provisions for partial retirement benefit obligations are recognised for all employees who are likely to start working on a part-time basis when approaching retirement age during the term of the framework agreement. The maximum thresholds for the employer's obligation indicated in the framework agreement are taken into account in this context. Amounts are valued at the present value of the probable obligations. Past experience has shown that the thresholds stated in the collective wage agreement have been exhausted.

The Biotest Group reports a share-based remuneration system under other provisions, which is posted according to IFRS 2.

#### **B14** Financial liabilities

Financial liabilities are reported at loan amount less transaction costs and subsequently carried at amortised cost in accordance with the effective interest rate method. Any difference between the net loan amount and the repayment value is shown over the term of the financial liability in the income statement.

#### **B15** Financial instruments

Financial instruments are contracts which result in a financial asset for one company and a financial liability or equity instrument for another company.

Financial assets comprise cash and cash equivalents, trade receivables and other loans granted and accounts receivable, financial investments held to maturity and primary and derivative financial assets held for trading.

Financial liabilities are regularly the basis for a claim for return in cash or cash equivalents or another financial asset. This includes, in particular, bonds and other securitised liabilities, trade payables, liabilities to banks, liabilities from finance leases, borrower's note loans and derivative financial instruments.

The Biotest Group uses currency option and currency forward transactions, interest rate caps and payer swaps to hedge against interest rate and currency risks. No derivative financial instruments are acquired for trading purposes.

Derivative financial instruments are valued at market value. The market values of currency option transactions, interest rate caps and payer swaps are determined by the banks on the basis of market conditions as of the balance sheet date. In the case of financial instruments held for hedging purposes, changes in the market values are reported on the basis of the type of hedging transaction. Since the stringent formal criteria for hedge accounting are not met in the Biotest Group, derivative instruments are reported in accordance with the rules for trading derivatives, despite a hedge being in place from a financial point of view. Derivative financial instruments are initially recorded at cost and subsequently at market value. The changes in valuation are recognised in the income statement.

#### B16 Revenue

Revenue from the sale of products is recognised at the time of transfer of economic ownership, that is at the time of transfer of the risks and rewards to the purchaser, based on the respective contractual agreements less any discount and VAT.

Customer-specific construction contracts are accounted for according to the percentage of completion method under IAS 11 "Construction Contracts". The service provided, including pro rata results, is reported under revenue according to the percentage of completion. The percentage of completion is determined according to the expenses incurred (cost-to-cost method). Contracts are reported under accounts receivable or liabilities according to the percentage of completion method.

Where the accumulated performance (contract cost and contract result) exceed payments received on account in individual cases, the construction contracts are reported on the assets side of the balance sheet under accounts receivable according to the percentage of completion method. If the balance after deducting payments received is negative, this is reported as a liability under construction contracts on the liabilities side of the balance sheet under liabilities according to the percentage of completion method. Anticipated contract losses which are determined taking account of discernible risks, are covered through write-downs or provisions.

#### B17 Research and development expenses

Research costs are recorded as expense at the time incurred. Development costs are also generally recorded as expense when incurred as it is not sufficiently certain that products may be marketed or production processes employed until they have been approved by the authorities and such approval is typically granted only at the end of the development process. The requirements for capitalisation pursuant to IAS 38 "Intangible Assets" are therefore generally not complied with in full. Development costs incurred after approval by the authorities are not material.

#### B18 Government grants for research and development

Government grants for research and development are recorded in the income statement at the time of the grant or in accordance with the research and development expense incurred. They are recorded under other income and not offset against the research and development expense.

#### B19 Financial income and expenses

Interest is recognised as expense or income when incurred. The interest component included in lease payments under finance leases is determined using the effective interest rate method and recognised as interest expense. The effective interest rate method uses a calculation interest rate with which the estimated future cash inflow is discounted over the expected life of the financial instrument to the net book value of the financial asset.

In accordance with IFRS 7, interest on financial instruments is also reported separately.

#### **B20** Taxes

The actual tax assets and tax liabilities for the current period and for earlier periods are to be valued at the amount at which a refund from or payment to the tax authorities is to be expected. The calculation of the amount reflects the tax rates and tax legislation of the respective national tax regulations of the countries in which the Biotest Group companies operate.

Active deferred taxes are recognised for all deductible temporary differences, as yet unused tax loss carryforwards and unused tax credits to the extent that it is probable that taxable income will be available against which the deductible temporary differences and as yet unused tax loss carryforwards and tax credits can be offset.

The book value of deferred tax assets is reviewed on each balance sheet date and reduced by the amount by which it is no longer probable that sufficient taxable income will be available to offset the deferred tax claim in part at least. In addition, deferred tax assets which have not been applied are reviewed on each balance sheet date and carried at the amount by which it is probable that future taxable income will facilitate the realisation of the deferred tax asset.

The respective current tax rates or those rates which were already passed by parliament are used to determine current tax expenses and deferred taxes.

Deferred tax assets and deferred tax liabilities are offset against each other if there are actionable claims for offsetting actual tax refund claims against actual tax liabilities and these refer to income tax with the same tax subject and are levied by the same tax authority.

#### **B21** Estimates

The preparation of the consolidated financial statements requires the use of estimates when reporting and measuring assets and liabilities in accordance with IFRS. These are reviewed on an ongoing basis. Prospective changes are recorded in the reporting period or in future periods. Assumptions and estimates are made in particular in connection with the measurement of goodwill, provisions, allowances for bad debts and on inventories, the measurement of share-based payments as well as in the determination of the fair values which apply. The material assumptions and parameters for the estimates made are disclosed in the notes.

#### C Segment reporting

Information disclosed in the segment report has been prepared in accordance with IFRS 8 "Operating Segments". No significant impact has resulted from the change in the reporting format from IAS 14 to IFRS 8.

Segmentation of the Biotest Group is primarily aligned along product lines in accordance with internal reporting. At Biotest AG, the chief operating decision maker within the meaning of IFRS 8 is the Board of Management. In addition, segment managers are responsible for each of the segments. They report to the chief operating decision maker, and their performance is measured on the basis of the income of the segment for which they are responsible and not on the overall performance of the Biotest Group. The Biotest Group has reported on five segments since financial year 2008. The former Diagnostics segment has been divided into Medical Diagnostics and Microbiological Monitoring. The previous year's figures have been adjusted accordingly. The former Pharmaceuticals segment was renamed Plasma Proteins. However, its original structure has been retained. No changes have been made to reporting on the Biotherapeutics segment. The segment "Corporate" does not constitute an operating segment in accordance with this standard and is therefore included in the reconciliation.

The segment information made available to the chief operating decision maker in periods of less than twelve months is based on the IFRS values and essentially comprises information up to operating profit (EBIT). Operating profit (EBIT) is used as a variable to assess segment performance. In order to measure assets, assets and liabilities are allocated to the segments on the basis of their economic origin at their respective IFRS book values.

The five business segments of the Biotest Group are as follows:

- Plasma Proteins: The Plasma Proteins segment researches, develops, manufactures and distributes drugs on the basis of human blood plasma. The preparations are used to treat diseases of the immune or haemopoietic systems.
- Medical Diagnostics: The Medical Diagnostics segment researches, develops, produces and markets products for blood group and tissue typing in medical laboratories.
- Microbiological Monitoring: The Microbiological Monitoring segment researches, develops, produces and markets products used in hygiene monitoring of air and surfaces in industry.

- **Biotherapeutics:** The Biotherapeutics segment researches, develops and produces monoclonal antibodies, including for the treatment of rheumatoid arthritis and multiple myeloma. In the Biotherpapeutics segment there are no sales until now.
- **Corporate**: The costs of the overriding Group management are shown separately in the Corporate segment. Assets contain other financial assets, income tax receivables, deferred tax assets and cash and cash equivalents. Liabilities pertain to bank loans for the financing of assets not assigned to the operating segments, income tax liabilities and deferred tax liabilities. In addition, expenses and earnings that cannot be assigned to other segments due to their uniqueness are reported in the Corporate segment. This segment does not constitute an operating segment within the meaning of IFRS 8.

Alongside segmentation by business segment, revenues are also shown according to segmentation by region. Segmentation of revenues by region was effected in accordance with the customer's geographical location and the registered office of the relevant company. Assets were allocated on the basis of the geographical location of the owner.

## Segment information by business segment

		Plasma	Medical	Micro- biological	Biothera-		
€ thousand		Proteins	Diagnostics	Monitoring		Reconciliation	Total
Revenue with third parties	2008	339,424	45,212	38,320	_	_	422,956
Revenue with third parties	2007	247,050	44,277	35,092	-	-	326,419
Operating profit (EBIT)	2008	81,212	- 3,256	4,954	- 16,733	- 10,538	55,639
operating prone (2011)	2007	60,759	-6,241	4,775	- 14,706	- 6,075	38,512
Assets	2008	496,001	46,213	24,496	2,909	22,425	592,044
1.55015	2007	445,855	42,805	25,137	59	22,846	536,702
Investments in associates	2008	23,089	5,444	2,383	4,152	1,471	36,539
investments in associates	2007	17,806	5,289	3,198	59	5,696	32,048
Liabilities	2008	222,313	44,748	12,021	24,682	34,906	338,670
Elabilities	2007	236,985	26,967	13,341	14,488	19,161	310,942
Scheduled depreciation	2008	18,448	3,177	1,547	2,285	448	25,905
and amortisation	2007	10,913	3,070	2,068	62	11	16,124
Non-scheduled depreciation	2008	327	-	-	-	-	327
and amortisation	2007	122	95	26	_	_	243

# Segment information by region

	Revenues with third parties according to customers' geographical location		according to	Revenues with third parties according to companies' registered office		urrent sets
€ thousand	2008	2007	2008	2007	2008	2007
Europe	281,358	261,976	346,690	316,070	190,774	182,027
America	63,913	13,994	74,132	8,687	121,359	112,506
Asia	66,869	45,649	2,134	1,662	420	277
Rest of world	10,816	4,800	-	_	-	_
Biotest Group	422,956	326,419	422,956	326,419	312,553	294,810
thereof:						
Germany	113,001	105,267	245,194	218,196	185,215	176,986
Abroad	309,955	221,152	177,762	108,223	128,351	117,824
thereof U.S.A.	57,105	8,938	74,132	8,687	121,359	112,506

There were no material supplies between the individual segments.

## D Explanatory notes to the income statement

#### D1 Revenue

€ thousand	2008	2007
Biotest Group products	389,811	300,944
Merchandise	14,152	14,376
Toll manufacturing	16,753	7,013
Revenue according to percentage of completion method	1,912	3,845
Other	328	241
	422,956	326,419

#### D2 Cost of materials purchased

€ thousand	2008	2007
Raw materials and supplies	128,149	82,193
Services purchased	15,486	10,438
	143,635	92,631

#### D3 Staff cost

€ thousand	2008	2007
Wages and salaries	94,413	69,491
Social security contributions	18,877	12,227
Pension costs	2,079	1,944
	115,369	83,662

The staff cost includes expenses for indemnification and severance pay of  $\leq 1,251$  thousand (2007:  $\leq 1,742$  thousand).

The average number of employees in terms of full-time equivalents amounted to 1,869 in financial year 2008 (2007: 1,340). As of 31 December 2008, the Biotest Group had 1,952.3 (2007: 1,726.5) employees in terms of full-time equivalents.

Employees are allocated to operating divisions as follows:

in full-time equivalents	2008	2007
Sales	398.2	381.0
Administration	246.0	246.8
Production	1,149.8	956.7
Research and development	158.3	142.0
	1,952.3	1,726.5

As of 31 December 2008, the Biotest Group employed 2,108 staff (2007: 1,877).

#### D4 Research and development expense

The research and development expense amounting to  $\notin$  43,676 thousand (2007:  $\notin$  34,476 thousand) was reported in full in the income statement.

## D5 Other operating income

€ thousand	2008	2007
Foreign exchange gains from operating activity	2,173	1,426
Release of deferred liabilities	1,698	1,689
Release of other provisions	806	1,069
Reversal of write-downs	386	114
Insurance reimbursement and other refunds	197	518
Refund of tax	118	-
Refunds from the Federal Employment Office for the replacement of positions due to		
partial retirement	99	30
Other earnings with associated companies	71	-
Gains from the disposal of fixed assets	28	12
Other	1,313	1,675
	6,889	6,533

## D6 Other operating expenses

€ thousand	2008	2007
Foreign exchange losses from operating activity	1,693	1,451
Unscheduled depreciation and amortisation	327	243
Write-downs of receivables	324	232
Additions to provisions	311	2,047
Cost of foreign exchange rate fixing	178	65
Indemnification	170	78
VAT expenses resulting from company audits	166	-
Donations	105	245
Losses from the disposal of fixed assets	13	42
Other	2,206	2,169
	5,493	6,572

#### D7 Financial income

€ thousand	2008	2007
Foreign exchange gains from financing activity	2,887	24
Interest income	168	739
Interest on tax refunds	16	-
Other	863	414
	3,934	1,177
thereof from financial instruments in the valuation categories according to IAS 39:		
Loans and accounts receivable (LaR)	972	474
Investments held to maturity (HtM)	5	4
Measurement of financial assets at fair value through profit and loss (FAFVtPL)	25	21

#### D8 Financial expenses

€ thousand	2008	2007
Interest expenses	11,702	5,210
Currency losses from financing activities	3,171	13
Interest expenses on pensions	2,295	1,806
Interest on tax payments	308	-
Amortisation of investments in associates	-	1,008
Other	1,565	1,312
	19,041	9,349
thereof from financial instruments in the valuation categories according to IAS 39:		
Financial liabilities measured at amortised cost (FLAC)	12,539	7,189

In the year 2007 the amortisation of investments in associates relates to the investment in BioDarou P.J.S. Co. reported as of 31 December 2007 in the amount of the pro rata equity of the company. The pro rata loss for the financial year 2007 (€184 thousand) is reported under costs relating to associated companies.

#### D9 Costs relating to associated companies

No costs relating to associated companies arose in financial year 2008. In the financial year 2007 the costs relating to associated companies of €184 thousand included a pro rata loss amounting to €184 thousand from the joint venture with BioDarou P.J.S. Co. with registered office in Teheran/Iran.

#### D10 Income tax

€ thousand	2008	2007
Taxes in the financial year	10,324	7,826
Current tax expense for previous years	96	757
Current taxes	10,420	8,583
Deferred taxes	1,993	4,296
Income tax expense	12,413	12,879

Deferred tax liabilities from items with direct negative or positive impact on equity amounted to €544 thousand (2007: €172 thousand).

Applying the nominal income tax rate of 28.8% (2007: 37.9%), the expected tax expense varies for financial year 2008 from the actual amounts as follows:

€ thousand	2008	2007
Profit before tax	40,532	30,156
Expected tax expense	11,673	11,429
Unvalued losses in the financial year	200	707
Utilisation of unvalued loss carryforwards from previous years	- 983	- 1,332
Deferred taxes on loss carryforwards from previous years	-	- 1,437
Write-downs on deferred tax assets	-	827
Tax payments for previous years	96	757
Tax effect from capitalisation of corporation tax credit	-	_
Tax effect from non-deductible expenses	667	636
Tax effect from future changes in domestic tax rates	234	1,527
Tax effect from the application of foreign tax rates and use of foreign tax losses carried forward	325	- 225
Tax effect from tax-free income	- 74	-17
Tax effect from capital increase costs	-	176
Other effects	275	- 169
Income tax in accordance with the income statement	12,413	12,879

The calculation of the tax rate of 28.8% is based on a corporation tax rate of 15%, a solidarity surcharge of 5.5% and the rate at which trade tax is levied by the municipality of Dreieich (registered office of the parent company).

#### D11 Auditors' expenses

Since KPMG Europe LLP merged with effect from 1 October 2007, KPMG LLP (UK) and KPMG Switzerland have been affiliated companies of KPMG AG Wirtschaftsprüfungsgesellschaft in accordance with Section 271 (2) of the German Commercial Code (HGB).

The Biotest Group incurred auditors' expenses to KPMG AG Wirtschaftsprüfungsgesellschaft totalling €633 thousand (2007: €388 thousand). These break down into fees of €333 thousand (2007: €281 thousand) for the audit, €214 thousand (2007: €96 thousand) for tax consultancy services and €83 thousand (2007: €8 thousand) for other audit-related services. Additionally there occurred further expenses for other services in the amount of €3 thousand (2007: €3 thousand).

#### D12 Operating profit of Biotest Pharmaceuticals Corporation

In financial year 2007, the operating profit of  $\leq -1,488$  thousand achieved by Biotest Pharmaceuticals Corporation in the period from 4 December to 31 December 2007 was shown separately in the income statement.

Operating profit for the acquired business was reported as a separate item showing an overall amount, since cost allocation according to uniform Group guidelines had not yet been implemented. In the notes to the income statement for 2007, the cost of materials purchased, staff costs and non-operating expenses and income of Biotest Pharmaceuticals Corporation were included.

In financial year 2008, the company's expenses and income were reported under all the relevant income statement items.

## E Explanatory notes to the balance sheet

## E1 Intangible assets

All assets listed below are allocated to non-current assets:

€ thousand	Goodwill	Patents, licences and similar rights	Leased assets	Facilities under construction	Total
Cost of purchase					
As of 31 December 2006	219	16,038	1,608	-	17,865
Additions to the scope of consolidation	26,926	37,125	-	-	64,051
Additions	-	5,571	-	-	5,571
Disposals	-	-170	-	-	-170
Currency translation differences	20	9	-	-	29
As of 31 December 2007	27,165	58,573	1,608	-	87,346
Additions	151	4,470	_	-	4,621
Disposals	-	- 5	-	-	- 5
Transfers	-	45	-	-	45
Currency translation differences	1,126	2,155	-	-	3,281
As of 31 December 2008	28,442	65,238	1,608	-	95,288
Accumulated depreciation					
As of 31 December 2006	_	11,180	1,217	-	12,397
Depreciation in the financial year	-	1,116	144	-	1,260
Depreciation and amortisation from PPA effect	_	321	_	_	321
Unscheduled depreciation and amortisation	_	_	243	_	243
Disposals	_	- 170	_	-	-170
Currency translation differences	-	- 61	_	-	- 61
As of 31 December 2007	-	12,386	1,604	-	13,990
Depreciation in the financial year	-	3,198	4	-	3,202
Depreciation and amortisation from PPA effect	_	3,710	_	_	3,710
Unscheduled depreciation and amortisation	_	327	_	_	327
Transfers	_	3	-	-	3
Currency translation differences	_	248	-	-	248
As of 31 December 2008	-	19,872	1,608	-	21,480
Book value as of					
31 December 2007	27,165	46,187	4	_	73,356
31 December 2008	28,442	45,366	_	-	73,808

No adjustments were required within the one-year allocation period as part of purchase price allocation (PPA) in relation to the acquired plasma protein activities of Nabi Pharmaceuticals.

Additional scheduled depreciation has arisen as a knock-on effect of the positive revaluation, which is reported separately in the statement of investments under depreciation from PPA effect.

There are contractual obligations amounting to €196 thousand (2007: €689 thousand) for the purchasing of intangible assets.

The additions to patents, licences and similar rights in the financial year amounting to €4,470 thousand (2007: €5,571 thousand) essentially relate to the costs for SAP software totalling €3,929 thousand (2007: €4,858 thousand).

With regard to the anti D project, the market launch in the indication of the autoimmune disease ITP (idiopathic thrombocytopenic purpura) was planned at the time of purchase price allocation. In the course of financial year 2008, the decision was made to abandon the market launch of the product in this indication, since the immunoglobulin already included in the portfolio can also be used for treatment in this indication. As a result of this decision, the intangible asset was subject to unscheduled amortisation in full with a value of USD455 thousand ( $\leq$ 327 thousand).

An impairment test was carried out in the Plasma Proteins cash generating unit in relation to two further development projects with an unlimited useful life and a book value of €9,964 thousand. The impairment test did not result in any unscheduled amortisation.

As a result of the realigned IT strategy, unscheduled amortisation of €243 thousand was applied to leased intangible assets in the financial year 2007.

The following items in the income statement include scheduled and unscheduled amortisation of intangible assets in the financial year:

€ thousand	2008	2007
Cost of sales	3,825	80
Distribution expenses	355	353
Administrative expenses	2,325	433
Research and development expenses	407	365
Other operating expenses	327	244
Operating profit Biotest Pharmaceuticals Corporation	-	349
	7,239	1,824

As in the previous year, no intangible assets are used to collateralise liabilities to banks under the new syndicated loan agreement from 2007.

To test for impairment, the goodwill acquired during mergers was allocated to the cash generating units, which correspond to the five segments. As a result of the increasing internationalisation of the business activities of heipha Dr. Müller GmbH and the associated links with other Biotest Group companies, heipha Dr. Müller GmbH was no longer treated as an independent cash generating unit from financial year 2007, but was instead allocated directly to the cash generating unit represented by the Diagnostics segment. Following the division of this segment in 2008, heipha Dr. Müller GmbH is allocated to the cash generating unit represented by Microbiological Monitoring from this financial year onwards.

The book values for goodwill are allocated to the individual cash generating units as follows:

Companies in the Biotest Group	Cash generating unit	Intangible assets	Book value as of 31 Dec 2008 in € thousand
Biotest Pharmaceuticals Corporation	Plasma Proteins segment	Goodwill	28,224
heipha Dr. Müller GmbH	Microbiological Monitoring segment	Goodwill	155
Biotest AG	Microbiological Monitoring segment	Goodwill	63
			28,442

The recoverable amount of the respective cash generating unit is determined through the calculation of a value in use on the basis of cash flow forecasts based on the several year financial planning drawn up by the company management. The after-tax discount rates of between 6% and 8% are based on the relevant weighted average cost of capital (WACC). The underlying growth rate in the calculation depends on the particular business and is between 0% and 2%. Necessary write-downs are determined by comparing the book value of the cash generating unit with the recoverable amount.

In the course of the annual impairment test, there was no requirement for any writedown on the individual cash generating units.

# E2 Property, plant and equipment

All assets listed below are allocated to non-current assets.

	Land and		Other plants, furniture and fixtures and	Leased	Facilities under	
€ thousand	buildings	Machinery	other equipment	assets	construction	Total
Cost of purchase/ cost of sale						
As of 31 December 2006	108,181	51,355	69,145	36,075	4,722	269,478
Additions to the scope of consolidation	34,258	20,333	1,261	_	12	55,864
Additions	1,061	6,130	5,973	979	12,334	26,477
Transfers	_	3,959	99	_	- 4,058	_
Disposals	-111	- 146	- 754	- 99	-	- 1,110
Currency translation differences	16	- 36	- 79	- 8	_	-107
As of 31 December 2007	143,405	81,595	75,645	36,947	13,010	350,602
Additions	2,493	9,047	10,356	179	9,843	31,918
Transfers	4,509	9,055	263	517	- 14,389	- 45
Disposals	-12	- 91	- 327	- 77	- 34	- 541
Currency translation differences	1,905	1,182	1	4	1	3,093
As of 31 December 2008	152,300	100,788	85,938	37,570	8,431	385,027
Accumulated depreciation						
As of 31 December 2006	37,267	30,013	44,052	11,477	-	122,809
Depreciation in the financial year	2,847	3,436	5,082	3,146	_	14,511
Depreciation from PPA effect	t –	32	-	-	-	32
Disposals	- 96	- 99	- 496	- 99	_	- 790
Currency translation differences	-16	- 64	-67	- 8	_	-155
As of 31 Dezember 2007	40,002	33,318	48,571	14,516	_	136,407
Depreciation in the financial year	3,240	6,498	5,877	3,018	-	18,633
Depreciation from PPA effect	t 6	354	_	-	-	360
Transfers	-	-15	12	_	_	- 3
Disposals	_	- 83	-210	- 77	-	- 370
Currency translation differences	-	154	- 53	4	_	105
As of 31 December 2008	43,248	40,226	54,197	17,461	-	155,132
Book value as of						
31 December 2007	103,403	48,277	27,074	22,431	13,010	214,195
31 December 2008	109,052	60,562	31,741	20,109	8,431	229,895

Within the one year allocation period there where no adjustments resulting from the purchase price allocation (PPA) in relation to the acquired plasma protein activities of Nabi Pharmaceuticals carried out for the annual account of 2007.

As part of this PPA, additional scheduled depreciation has arisen as a knock-on effect of the positive revaluation, which is reported separately in the statement of investments under depreciation from PPA effect.

Depreciation on property, plant and equipment for financial year 2007 includes depreciation of the Biotest Pharmaceuticals Corporation amounting to  $\notin$ 248 thousand. Total depreciation on property, plant and equipment of the company in 2007 of  $\notin$ 280 thousand is reported in the income statement under the item Operating profit Biotest Pharmaceuticals Corporation.

Government grants for purchasing or production of assets reduce the cost of purchase and cost of sales. In financial year 2008, the accumulated reduction amounted to €766 thousand (2007: €699 thousand).

Assets capitalised as finance leases primarily relate to production facilities of Biotest AG for plasma fractionation and sterile final fill. The sterile final fill was completed in financial year 2002 and depreciation was recorded for the first time in the same year. The plasma fractionation facility started operations in 2004. The term of the lease contracts for the two facilities amounts to eight years in each case. Biotest may terminate the contracts with three months' notice. The earliest possible date, however, is a date on which at least 40% of the contractual term has passed. Biotest only has the right of termination prior to expiry of 90% of the contractual term if Biotest provides evidence of exceptional circumstances with regard to the possibility or ability to utilise the facilities. After expiry of the contracts, Biotest may purchase the facilities at market value.

Collateral for the syndicated loan agreement existing since 2007 was provided by a charge of €95 million on real estate belonging to Biotest AG, Biotest Pharma GmbH and Biotest Grundstücksverwaltungs GmbH as third party assignor. The creation of a global charge on real estate belonging to the company and its subsidiaries of €100 million was notarised on 18 March 2003 as part of an earlier collateral trustee agreement. Moreover, shares in the Biotest Pharmaceuticals Corporation were pledged as collateral.

In the financial year 2008, facilities under construction primarily consist of the production plant for the R&D project IVIG at Biotest Pharmaceuticals Corporation. In the previous year this item primarily consisted of partial payments settled of  $\leq$ 12,371 thousand for the expansion of the IG-CP facility (facility for chromatographic purification of immunoglobulins) and the adjustment of production functions.

#### E3 Investments in affiliates

Investments in affiliates amounting to €100 thousand break down as follows:

€ thousand	2008	2007
Biotest Hycon GmbH	50	50
Biotest Immobilien Verwaltungs GmbH	25	25
Biotest Immobilien GmbH & Co. KG	25	25
Biotest Medical Diagnostics GmbH	-	55
	100	155

Biotest Hycon GmbH is a wholly-owned subsidiary of Biotest AG. Biotest Immobilien Verwaltungs GmbH and Biotest Immobilien GmbH & Co. KG are wholly-owned subsidiaries of Biotest Pharma GmbH. The companies are not operationally active and are therefore not consolidated for negligibility reasons. Biotest Medical Diagnostics GmbH is a wholly-owned subsidiary of Biotest AG and fully consolidated in the financial year 2008.

#### E4 Investments in associates

Investments in associates refer to the 49% stake held by Biotest Pharma GmbH in BioDarou P.J.S. Co. with registered office in Teheran/Iran, which is valued using the equity method.

Investments in associates in the amount of  $\leq$ 1,015 thousand where fully depreciated in 2007.

The object of the company is the collection of plasma and its processing into immunoglobulins, factors and human albumin at Biotest.

In the first stage, the partners in the joint venture intend for the company to gradually be equipped with equity of up to €4,000 thousand. The respective required shareholder resolutions are adopted separately according to the financial requirement. To date, Biotest Pharma GmbH has paid a contribution of €796,572 (2007: €796,572). The capital of BioDarou P.J.S. Co. amounts to 30 billion rial (2007: 30 billion rial) and is fully paid up.

Given that no audited financial statements were available for BioDarou P.J.S. Co. as of the time of preparing the consolidated financial statements, the previous year's figures are reported for BioDarou P.J.S. Co. The earnings forecast of BioDarou P.J.S. Co. for financial year 2008 showed a balanced result and the company's balance sheet structure was similar to that of financial year 2007. In financial year 2008, no capital measures were implemented.

The joint venture had the following assets and liabilities as of the balance sheet date 2007:

The value of non-current assets amounted to €3,998 thousand (2006: €4,544 thousand) as of 31 December 2007 and the value of current assets amounted to €1,290 thousand (2006: €1,693 thousand).

The value of non-current liabilities amounted to  $\leq 2,694$  thousand (2006:  $\leq 3,410$  thousand) as of 31 December 2007 and the value of current liabilities amounted to  $\leq 1,290$  thousand (2006:  $\leq 1,891$  thousand).

In financial year 2007, the company reported a loss of €376 thousand (2006: €737 thousand).

In financial year 2008, the company made several deliveries of Iranian plasma available to Biotest AG free of charge for the purpose of having finished products manufactured for the Iranian market.

The company intends to increase blood plasma collection further in financial year 2009. On this basis, the company expects sales growth, which will be accompanied by the corresponding positive development in income.

The company's success in 2009 will ultimately depend on the extent to which the decline in oil prices will impact on financing of the health system in Iran. In addition, the future political situation in Iran will affect the company's future opportunities.

In view of the fact that the financial basis of Iran depends on crude oil and given the existing international restrictions, the assessment of the company's future prospects remains cautious.

#### E5 Other financial assets

€ thousand	2008	2007
Bond funds (Financial Assets at Fair Value through Profit and Loss)	136	130
Fixed-income securities (Held to Maturity)	87	111
Loans to employees (Loans and Receivables)	14	17
	237	258

In financial years 2008 and 2007, financial instruments were not reclassified.

The fair value of the Financial Assets at Fair Value through Profit or Loss category comprises fund units; their fair value as of the balance sheet date is advised by the custodial bank in writing.

The fair value of the Held to Maturity category, which includes fixed-term deposits, corresponds to the nominal value.

The Loans and Receivables category includes loans to employees; the fair value is set at the nominal value.

#### E6 Deferred tax assets and deferred tax liabilities

The deferred tax assets and deferred tax liabilities refer to the following items on the balance sheet:

		Assets	Equity	and liabilities		Net
€ thousand	2008	2007	2008	2007	2008	2007
Intangible assets	269	95	444	414	- 175	- 319
Property, plant and equipment	10	14	15,881	13,549	- 15,871	- 13,535
Other financial assets	495	361	20	91	475	270
Inventories	8,138	5,698	370	36	7,768	5,662
Trade receivables	46	20	3,161	2,272	- 3,115	- 2,252
Provisions	781	1,320	33	37	748	1,283
Financial liabilities	2,678	4,051	384	436	2,294	3,615
Other liabilities	3,356	1,170	13	119	3,343	1,051
Other balance sheet items	503	3,155	112	17	391	3,138
Tax value of the loss carried forward	3,716	3,178	_	_	3,716	3,178
Sub-total	19,992	19,062	20,418	16,971	- 426	2,091
Less deferred tax assets set off against deferred tax liabilities	- 14,002	- 13,191	- 14,002	- 13,191	_	_
Deferred tax assets/liabilities	5,990	5,871	6,416	3,780	- 426	2,091

Deferred taxes have not been recognised for tax loss carryforwards of  $\leq 1,131$  thousand (2007:  $\leq 3,001$  thousand), as we currently do not expect with sufficient certainty to be able to use such loss carryforwards. Deferred taxes not recognised for loss carryforwards of  $\leq 1,131$  thousand (2007:  $\leq 2,018$  thousand) are attributable to German companies and with  $\leq 0$  (2007:  $\leq 983$  thousand) to foreign companies. At present, loss carryforwards can be carried forward for an unlimited time in Germany.

#### **E7** Inventories

€ thousand	2008	2007
Raw materials and supplies	29,438	22,573
Work in progress	74,940	59,622
Finished goods and merchandise	52,176	34,676
	156,554	116,871

Write-downs on inventories amounted to €9,155 thousand (2007: €5,806 thousand) as of the balance sheet date; after the write-down to the net realisable value, the corresponding inventories had a residual book value of €23,024 thousand (2007: €17,997 thousand).

As in the previous year, no inventories were used as collateral for liabilities to banks in the syndicated loan agreement signed in financial year 2007.

Inventories with a reach of more than one year are recorded at a book value of  $\notin$  2,906 thousand (2007:  $\notin$  2,534 thousand).

The breakdown of impairment losses on inventories is as follows:

€ thousand	2008	2007
As of 1 January	5,806	3,910
Utilisations	- 1,203	- 2,216
Releases	- 1,395	- 66
Additions	5,739	4,183
Foreign exchange differences	208	- 5
As of 31 December	9,155	5,806

#### E8 Trade receivables

Trade receivables are normally due within one year. In the current financial year, of a total of €94,481 thousand, trade receivables amounting to €451 thousand have been classified as long term. Trade receivables are allocated to the "Loans and Receivables" (LaR) category. They comprise the following items:

€ thousand	2008	2007
Trade receivables (gross)	123,698	122,691
Sale of receivables	- 26,154	- 18,581
Allowance for bad debts	- 3,063	- 2,969
Trade receivables (net)	94,481	101,141

The allowance for bad debts is determined as the difference between the nominal value of the accounts receivable and the estimated recoverable net amount. For the estimate, the Biotest Group uses historical values relating to the payment behaviour of specific customers and knowledge about country-specific circumstances. When determining the value of trade receivables, account is taken of all changes in credit ratings since granting the payment target and up to the balance sheet date. This applies to changes in country risks and specific customer risks. For write-downs on trade receivables, the Biotest Group exclusively uses specific bad debt charges. General bad debt charges are not applied.

Under factoring contracts, Biotest AG disposed of accounts receivable in the amount of €13,946 thousand (2007: €8,770 thousand) as of the balance sheet date. The factoring programme provides for the sale of domestic and foreign accounts receivable of Biotest AG, whereby each customer has an individual credit limit. Provided that the accounts receivable are legally valid, the factor carries the risk of the customer's inability to pay the accounts receivable purchased (risk of default).

Furthermore and as in 2007, these contracts provide for the sale of accounts receivable from private hospitals in Greece by Biotest Hellas MEPE. In this connection, accounts receivable totalling €12,189 thousand (2007: €8,169 thousand) are reported under other assets.

As in the previous year, no accounts receivable served as collateral for liabilities to banks as of the balance sheet date.

Trade receivables include accounts receivable according to the percentage of completion method amounting to €5,756 thousand (2007: €3,845 thousand). These relate to customer-specific construction contracts which are valued at the corresponding cost of sales incurred including pro rata profit.

As of the reporting date, the Biotest Group as lessor carried finance lease receivables of €507 thousand as part of TANGO® optimo leasing services. The underlying lease agreements generally have a term of five years. The repayable amounts total €562 thousand before deduction of accrued interest. Of this, €111 thousand is due in less than one year, €439 thousand within the following four years and €12 thousand after five or more years.

The allowance for doubtful trade receivables and accounts receivable according to the percentage of completion method developed as follows:

€ thousand	2008	2007
As of 1 January	2,969	4,142
Additions	558	285
Utilisations	- 92	- 1,207
Releases	- 368	- 251
Foreign exchange differences	-4	_
As of 31 December	3,063	2,969

The analysis of the age of trade receivables provides the following information:

€ thousand	2008	2007
Book value	94,481	101,141
thereof not impaired and not overdue as of the reporting date	61,801	70,715
thereof not impaired and overdue in the following periods		
< 90 days overdue	13,855	17,837
91 – 180 days overdue	6,808	4,879
181 – 365 days overdue	4,653	4,647
> 1 year overdue	562	2,839

Of the overdue accounts receivable by the Biotest Group in financial year 2008, €16,252 thousand (2007: €16,638 thousand) relate to accounts receivable of Biotest Italia S.r.l. and Biotest Hellas MEPE. Due to country-specific payment procedures, overdue accounts receivable are common practice in these locations. The creditworthiness of the debtors is essentially ensured, since these accounts receivable are accounts receivable from state-run hospitals and it can therefore be assumed that the outstanding amounts will be paid.

Net trade receivables are denominated in the following currencies:

€ thousand	2008	2007
EUR	77,125	82,411
USD	13,532	13,586
GBP	906	1,592
HUF	1,520	2,570
Other currencies	1,398	982
Trade receivables (net)	94,481	101,141

#### E9 Other assets

	2008		:	2007
€ thousand	Total	thereof non-current	Total	thereof non-current
Trade reveivables from factoring companies	12,189	-	8,169	_
Value-added and other tax claims	2,988	79	850	97
Deferred items	2,072	141	3,230	233
Trade receivables from associated companies	1,107	1,107	_	_
Loans to employees	313	135	306	-
Derivatives	279	244	414	335
Trade receivables from insurance companies	236	150	337	144
Payments in advance	224	64	158	_
Other assets	1,057	152	1,276	166
	20,465	2,072	14,740	975

#### Allowances for other assets developed as follows:

€ thousand	2008	2007
As of 1 January	964	964
Additions	-	-
Utilisations	-	-
Releases	-	-
Currency translation differences	-	-
As of 31 December	964	964

#### The analysis of the age of other assets provides the following information:

€ thousand	2008	2007
Book value	20,465	14,740
thereof not impaired and not overdue as of the reporting date	20,300	14,697
thereof not impaired and overdue in the following periods		
< 90 days overdue	-	-
91 – 180 days overdue	-	-
181 – 365 days overdue	-	-
> 1 year overdue	-	-

In financial year 2008, the Biotest Group achieved income from operating leases amounting to  $\leq 186$  thousand. According to the valid operating lease agreements as of the balance sheet date, lease income of  $\leq 681$  thousand results for financial year 2009 and for the subsequent four financial years a total amount of  $\leq 2,207$  thousand. From financial year 2014 onwards, there will be no income from operating leases.

Other assets are denominated in the following currencies:

€ thousand	2008	2007
EUR	18,351	11,691
USD	1,574	2,543
GBP	146	94
HUF	233	206
Other currencies	161	206
	20,465	14,740

#### E10 Cash and cash equivalents

€ thousand	2008	2007
Bank balances	7,302	8,748
Cash on hand	770	141
	8,072	8,889

Please refer to the cash flow statement of the Biotest Group for details regarding the development of cash and cash equivalents.

#### E11 Equity

The subscribed capital is fully paid up and amounted to  $\leq 30,025,152$  (ordinary shares:  $\leq 16,883,819.52$ ; preference shares:  $\leq 13,141,332.48$ ) as of 31 December 2008. As of that date, it was divided into 6,595,242 ordinary shares of no-par value and 5,133,333 preference shares of no-par value and without voting rights. Certification of shares is precluded. The theoretical nominal value of these shares therefore amounted to  $\leq 2.56$ . In the previous year, the subscribed capital amounted to  $\leq 30,025,152$  (ordinary shares:  $\leq 16,883,819.52$ ; preference shares:  $\leq 13,141,332.48$ ) and was divided into 6,595,242 ordinary shares and 5,133,333 preference shares. The distributable profit of Biotest AG determined in accordance with the German Commercial Code is the basis for the profit distribution in any financial year.

In her letter dated 8 February 2008, Dr. Cathrin Schleussner advised us that her share of the voting rights as of that day amounted to 50.03%. The voting rights are held via OGEL GmbH, Frankfurt/Main. OGEL GmbH is controlled by Dr. Cathrin Schleussner. On 3 December 2008, Massachusetts Mutual Life Insurance Company, Massachusetts/USA, advised that its shareholding exceeded the 3% threshold as of 28 November 2008 and that the company now holds 3.18% of the voting rights. As of the reporting date of 31 December 2008, Kreissparkasse Biberach held 24.36% of the company's ordinary shares according to its latest notification.

The proposed appropriation of profits provides for a dividend distribution of  $\in$ 3,827 thousand in 2008. The dividend on ordinary shares amounts to  $\in$ 0.30/share and on preference shares  $\in$ 0.36/share. Preference shares carry minimum dividend rights of  $\in$ 0.11/share. Moreover, should holders of ordinary shares receive a dividend of more than  $\in$ 0.11/share, holders of preference shares receive an additional dividend of  $\in$ 0.06/share. If no dividend is paid on preference shares in one year, this must be paid in the following year. If the dividends are not paid in the second year, the preference shares are furnished with voting rights (cf. Section 140 (2) of the German Stock Corporation Act (AktG)).

By resolution of the Annual Shareholders' Meeting held on 27 May 2008, Biotest AG was authorised to purchase own ordinary and/or preference shares pursuant to Section 71 (1) No. 8 of the German Stock Corporation Act (AktG) until 26 November 2009 up to 10% of the capital stock at the time of the resolution in the amount of €30,025 thousand. Moreover, with the consent of the Supervisory Board, the Board of Management was authorised by resolution of the Annual Shareholders' Meeting on 20 May 2005 to increase the capital stock of Biotest AG by up to €10,240 thousand through the issue of new ordinary and preference shares in return for contributions in cash or in kind (authorised capital) up until 19 May 2010. Following the capital increase on 28 September 2007, the authorised capital amounts to €695 thousand.

Issuance can take place once or on several occasions, whereby shareholders' subscription rights may be excluded. In addition, the Board of Management was authorised with the consent of the Supervisory Board to issue profit-sharing rights until 7 July 2009 with a nominal amount of up to €50,000 thousand. Use was made of this authorisation in financial year 2005 in the amount of €10,000 thousand.

Earnings per share are determined by dividing the consolidated profit attributable to all shareholders by the weighted average number of shares outstanding.

€ thousand	2008	2007
Profit for the period	25,742	15,522
Additional dividend on preference shares	- 308	- 287
Consolidated earnings adjusted for additional dividend rights	25,434	15,235
Number of shares outstanding (corresponds for weighted average)	11,728,575	10,939,855
Earnings per share in €	2.17	1.39
Additional dividend rights per preference share in €	0.06	0.06
Earnings per preference share in €	2.23	1.45

# Statement of changes in equity of the Biotest Group for the period from 1 January to 31 December

€ thousand	Subscribed capital	Share premium	Accumulated differences from currency translation	Earnings and reserves	Equity before minority interest	Minority interests	Total equity
	Capitai	premium	translation	reserves	interest	IIILEIESIS	equity
As of 1 January 2007	27,296	122,922	- 863	27,282	176,637	2,676	179,313
Gains/losses recognised	•	,				,	
immediately in equity	_	-	- 483	525	42	28	70
Profit for the period	_	-	-	15,522	15,522	1,755	17,277
Total result	_	_	- 483	16,047	15,564	1,783	17,347
Capital increase Biotest AG	2,729	30,410	_	_	33,139	_	33,139
Acquisition of minority interests				- 8	- 8	11	3
Dividend payments for 2006				- 2,839	- 2,839	- 1,203	- 4,042
As of				2,000		2,200	.,
31 Devember 2007	30,025	153,332	- 1,346	40,482	222,493	3,267	225,760
As of 1 January 2008	30,025	153,332	-1,346	40,482	222,493	3,267	225,760
Gains/losses recognised immediately in equity	l 	_	3,443	1,095	4,538	8	4,546
Profit for the period	_	_	_	25,742	25,742	2,377	28,119
Total result	_	_	3,443	26,837	30,280	2,385	32,665
Acquisition of minority interests	-	_	_	-21	- 21	- 41	- 62
Dividend payments for 2007	_	_	_	- 3,827	- 3,827	- 1,162	- 4,989
As of 31 December 2008	30,025	153,332	2,097	63,471	248,925	4,449	253,374

#### E12 Pension provisions and similar obligations

The benefits are based on the employee's length of service and salary. Retirement benefit obligations are essentially recognised for employees in German and Greek companies. Similar obligations include foreign obligations which become due in the form of a one-time payment upon retirement.

Pension provisions and similar obligations consist of the following:

€ thousand	2008	2007
Pensions	42,137	41,892
Similar obligations	1,251	1,211
	43,388	43,103

#### The net amount of pension provisions and similar obligations is derived as follows:

€ thousand	2008	2007
Present value of retirement benefit obligations funded by provisions	43,275	42,923
Present value of retirement benefit obligations funded by pensions liability insurance	852	857
Fair value of plan assets (employer's pension liability insurance)	- 739	- 677
Present value of retirement benefit obligation	43,388	43,103

During the period under review, the value of pension provisions at Group level changed as follows:

€ thousand	2008	2007
Pension provisions as of 1 January	43,103	43,123
Pension payments in the reporting period	- 2,315	- 1,999
Release of pension provisions for persons no longer eligible for benefits	- 4	- 10
Pension costs	4,360	3,308
Actuarial gains recognised in equity	- 1,756	- 1,319
Pension provisions as of 31 December	43,388	43,103

Defined benefit plans generated overall expenses of €4,360 thousand during the reporting year (2007: €3,308 thousand), comprising the following components:

€ thousand	2008	2007
Current service cost	1,587	1,501
Service period costs to be charged retrospectively	478	-
Changes in the fair value of plan assets (employer's pension liability insurance)	-61	- 85
Interest expense	2,356	1,892
	4,360	3,308

In financial year 2008, actuarial gains amounting to  $\leq 1,756$  thousand (2007:  $\leq 1,319$  thousand) were recognised in equity.

Pension costs are included in the following items in the income statement:

€ thousand	2008	2007
Cost of sales	905	657
Distribution expense	457	345
Administrative expense	384	289
Research and development expense	319	211
Financial expenses	2,295	1,806
	4,360	3,308

The calculations are based on the following actuarial assumptions:

in %	2008	2007
Discount rate as of 31 December	5.5 – 6.3%	5.5 – 5.7%
Expected return on plan assets	2.0-6.0%	4.1 - 4.5%
Salary progression	1.5 — 3.5%	1.5 — 3.5%
Pension progression	1.5 - 2.0%	1.5 - 2.0%
Staff turnover rate	3.0 - 4.5%	3.0 - 4.5%

The actuarial assumptions are based on empirical values.

The following table shows the reconciliation account for the present value of the defined benefit obligation (DBO):

€ thousand	2008	2007
Defined benefit obligation as of 1 January	43,780	43,799
Current service cost	1,587	1,501
Interest expense	2,356	1,892
Actuarial gains and losses	-1,756	- 1,319
Service period costs to be charged retrospectively	478	-
Pensions paid	- 2,318	- 2,093
Defined benefit obligation as of 31 December	44,127	43,780

The following table shows the reconciliation account for the present value of the plan assets:

€ thousand	2008	2007
Present value of plan assets zum 1 January	677	676
Expected return on plan assets	60	60
Acuarial gains and losses	- 2	- 5
Employer's constribution	4	17
Pension paid	-	- 71
Present value of plan assets as of 31 December	739	677

The actual income from plan assets amounted to  $\in$  30 thousand in the financial year (2007:  $\in$  61 thousand).

As in the previous year, plan assets exclusively comprise insurance contracts.

IAS 19.120A p) requires the presentation of an overview of the current year and preceding four years:

€ thousand	2008	2007	2006	2005	2004
Present value of the defined benefit obligation (DBO)	44,127	43,780	43,799	42,992	37,286
Fair value of plan assets	739	677	676	629	766
Expectation-related adjustments:					
a) plan liabilities	1,273	861	1,501	2,226	3,701
b) plan assets	- 2	- 8	- 32	- 8	7

In the financial year under review,  $\leq 6,534$  thousand (2007:  $\leq 6,036$  thousand) were recorded in connection with contribution-based pension plans.

The breakdown of expenses for contribution-based pension plans is as follows:

€ thousand	2008	2007
Constribution-based pension plans of the company	231	182
Employer contributions to statutory pension insurance	6,303	5,854
	6,534	6,036

#### E13 Other provisions

€ thousand	Partial retire- ment	Other staff- related costs	Other	Total	thereof short- term
As of 31 December 2007	2,947	10,082	6,403	19,432	16,787
Additions	1,608	9,083	5,519	16,210	
Utilisations	- 2,377	- 7,847	- 1,622	- 11,846	
Releases	_	- 521	- 285	- 806	
Transfers	_	119	- 119	-	
Currency translation differences	_	3	36	39	
Addition of accrued interest	12	- 52	- 66	-106	
As of 31 December 2008	2,190	10,867	9,866	22,923	19,270

The corresponding provision has been recognised pursuant to the collective agreement to promote partial retirement of Bundesarbeitgeberverband Chemie e.V., which runs until 31 December 2009. In addition to obligations for current partial retirement arrangements (performance backlog, top-up amounts and severance payments if required), the provision includes funds for anticipated future drawdowns (top-up amounts and severance payments if required).

The other staff-related provisions essentially comprise provisions for profit sharing, anniversaries and contributions to the employer's liability insurance association.

Other provisions include provisions for the Long Term Incentive Programme as well as the negative fair value of derivative financial instruments, the utilisation of guarantees, process risks and similar facts.

The additions in financial year 2008 essentially comprise additions to profit sharing by employees totalling €7,852 thousand, to the Long Term Incentive Programme amounting to €1,538 thousand and to partial retirement benefits of €1,620 thousand.

At  $\in$  347 thousand, the release of other provisions mainly relates to profit sharing by employees.

The impact of changes to the discount rate on the present value of the previous year amounts to  $\in$  360 thousand.

#### E14 Financial liabilities

€ thousand	2008	2007
Non-current liabilities		
Collateralised liabilities to banks	145,144	138,535
Unsecured subordinated loans	17,310	15,015
Unsecured other loans	416	378
Liabilities from finance leases	3,778	8,762
	166,648	162,690
Current liabilities		
Collateralised liabilities to banks	_	_
Other collateralised liabilities to banks	16,973	16,849
Short-term portion of collateralised liabilities to banks	16,973	16,849
Other collateralised loans	_	
Other unsecured loans	3,794	3,624
Other loans	3,794	3,624
Short-term portions of liabilities from financial leases	5,688	5,460
Unsecured liabilities to banks	1,737	136
	28,192	26,069

With the exception of the short-term portion of liabilities from finance leases, the balance sheet values of current financial liabilities correspond approximately to the market values because of their short maturities.

The syndicated loan agreement includes a short-term tranche of  $\leq 40$  million, a long-term tranche of  $\leq 85$  million with full amortisation within seven years, as well as a bullet tranche of  $\leq 50$  million which is due in 2015.

Of the credit lines granted under the syndicated loan agreement, €32,210 thousand remained unused in 2008 (2007: €32,775 thousand). In addition, unused credit lines amounting to €36,936 thousand (2007: €27,565 thousand) are available.

Information on hedging exchange rate and interest risks is given in section F2 Financial instruments.

Via the profit-participation certificate dated 25 November 2005, unsecured subordinated loans essentially include a bullet loan (nominal amount:  $\leq 10,000$  thousand) in the amount of  $\leq 9,809$  thousand (2007:  $\leq 9,762$  thousand), for which a subordinated claim was extended. The return on this loan depends on the key financial figures. The loan was disbursed minus a discount. Moreover, the subordinated loan amounting raised in financial year 2007 was increased in the financial year 2008 by  $\leq 2,247$  thousand up to  $\leq 7,500$  thousand.

In connection with the syndicated loan agreement, Biotest AG is obliged to maintain certain financial ratios. These apply to both a certain ratio of net debt to EBITDA, to a certain ratio of net debt to liable equity and to a ratio of EBITDA to interest expense. These financial ratios are determined quarterly to the end of the quarter based on the annual or quarterly consolidated financial statements.

Terms, redemption terms of financial liabilities and the structure of times to maturity are as follows:

€ thousand		Time to maturity	Time to maturity 1 to 5	Time to maturity
2008	Total	<1 year	years	> 5 years
Collateralised liabilities to banks:				
Euro – floating between 1.3 to 5.7%	79,744	5,168	24,112	50,464
Euro – fixed between 3.8 to 6.4%	20,555	7,471	8,350	4,734
USD – floating between 1.3 to 3.8%	61,819	4,335	53,891	3,593
Other loans:				
Euro – floating between 4.5 to 6.7%	3,394	3,344	-	50
Euro – fixed between 3.3 to 6.0%	815	449	56	310
Liabilities from finance leases:				
Euro – fixed between 3.0 to 7.4%	9,466	5,688	3,692	86
Unsecured loans:				
Euro – floating between 3.2 to 7.0%	10,258	448	9,810	_
Euro – fixed between 3.6 to 6.7%	8,250	750	1,250	6,250
USD – floating of 1.9%	539	539	-	-
	194,840	28,192	101,161	65,487

Terms, redemption terms of financial liabilities of the previous year and the structure of times to maturity are as follows:

€ thousand 2007	Total	Time to maturity <1 year	Time to maturity 1 to 5 years	Time to maturity > 5 years
Collateralised liabilities to banks:				
Euro – floating between 3.5 to 6.5%	84,703	10,650	16,147	57,906
Euro – fixed between 3.8 to 8.3%	9,659	2,918	3,973	2,768
USD – floating between 5.8 to 7.3%	61,019	3,278	37,362	20,379
GBP – floating between 6.9 to 7.3%	3	3	-	-
Other loans:				
Euro – floating between 3.3 to 9.3%	2,317	2,317	-	-
Euro – fixed between 5.0 to 5.5%	706	328	53	325
USD – fixed at 5.6%	979	979	-	-
Liabilities from finance leases:				
Euro – fixed between 3.0 to 7.0%	14,222	5,460	8,685	77
Unsecured loans:				
Euro – floating between 6.9 to 7.0%	9,796	34	9,762	-
Euro – fixed between 1.8 to 3.6%	5,355	102	-	5,253
	188,759	26,069	75,982	86,708

### Liabilities from finance leases are amortised as follows:

€ thousand	Payment	Interest	Amortisation
2008			
Due in < 1 year	6,316	628	5,688
Due in 1 to 5 years	4,017	325	3,692
Due in > 5 years	88	2	86
	10,421	955	9,466
2007			
Due in < 1 year	6,304	844	5,460
Due in 1 to 5 years	9,520	835	8,685
Due in > 5 years	79	2	77
	15,903	1,681	14,222

Collateral for the new syndicated loan agreement was provided by a charge of €95 million on real estate belonging to Biotest AG, Biotest Pharma GmbH and Biotest Grundstücksverwaltungs GmbH as third party assignor. The creation of a global charge on real estate belonging to the company and its subsidiaries of €100 million was notarised on 18 March 2003 as part of an earlier collateral trustee agreement. Moreover, shares in the Biotest Pharmaceuticals Corporation were pledged as collateral.

## E15 Other liabilities

€ thousand	2008	2007
Commission payable	6,202	8,091
Value added tax liabilities	3,344	3,206
Deferred liabilities	2,266	2,319
Wage tax liabilities	1,756	1,523
Social security liabilities	573	457
Liabilities from other taxes	-	21
Other liabilities	3,338	1,101
Deferred items	215	237
	17,694	16,955

In this financial year, there are additional other liabilities with a remaining time to maturity of over one year of  $\leq 220$  thousand (2007:  $\leq 0$  thousand).

### F Other explanatory notes

### F1 Long Term Incentive Programme

Biotest AG pursues a business policy focused on the interests of shareholders in terms of the shareholder value principle, which promotes the long-term value enhancement of the Biotest Group. As in the previous two years, with the consent of the Supervisory Board, the company therefore resolved to continue the Long Term Incentive Programme (LTIP) with a further tranche in 2008. The LTIP consists of the tranches 2006, 2007 and 2008.

The subsidiary Biotest Pharmaceuticals Corp. which had taken over the US Plasma business from Nabi Biopharmaceuticals in December 2007 was as well integrated into the Long Term Incentive Programme in a slightly modified way.

#### Long Term Incentive Programme/2008 tranche

The programme was launched on 1 May 2008 and runs until 31 December 2010. The structure of this tranche is largely the same as the tranche issued in 2006 and 2007.

Participation in the programme is contingent on the participant's personal investment through the purchase of preference shares in Biotest AG. 25% of the acquisition was supported by Biotest AG. Participants were able to either retain or use as their personal investment those preference shares already acquired in 2006. The personal investment in preference shares is to be held in the custody account until the incentive payment is disbursed. For participants from Biotest Pharmaceuticals Corp. there's no personal investment required due to special legal reasons resulting form U.S. law. On expiry of the programme, each beneficiary will receive an incentive payment in cash after the Annual Shareholders' Meeting scheduled for May 2011; this cash payment will depend on the level of own investment, the fixed salary as of 1 October 2008 and the achievement of two performance targets. The performance targets are allocated to factors by which the own investment is multiplied.

The level of the incentive payment is calculated in accordance with the following formula:

own investment x performance factor 1 + own investment x performance factor 2 ------ x

100

annual fixed salary as of 1 October 2008 = payment

The level of the performance factors derives from the extent to which the company has achieved agreed performance targets.

Performance target 1 refers to the development of the share price compared to a relevant comparative parameter. Here the performance of Biotest preference shares is compared to shares listed on the SDAX.

Position vs. benchmark (shares SDAX)	Performance factor 1
Better than 3 <sup>rd</sup> quartile	0.04
Same as median	0.02
Better than 1 <sup>st</sup> quartile	0.01
Worse/same as 1 <sup>st</sup> quartile	0.00

However, the key criterion for performance factor 1 is that in financial year 2010, the company achieves earnings before interest and tax (EBIT) of at least  $\leq$ 10,000 thousand before taking account of the LTIP. If EBIT remains below  $\leq$ 10,000 thousand in 2010, the factor is 0.

Performance target 2 relates to the average EBIT margin achieved in the years 2008, 2009 and 2010 based on the total of the annual EBIT margins divided by three.

Performance factor 2 is also linked to another key criterion. The factor only comes into effect when the price of Biotest preference shares has outperformed the 1<sup>st</sup> quartile of the SDAX shares during the term. The calculation is carried out in the same way as for performance factor 1.

Average EBIT marge 2008–2010	Performance factor 2
16.3% and higher	0.04
Equal to 12.8%	0.02
At least 10.9%	0.01
Below 10.9%	0.00

For targets achieved that lie between the values indicated above, the respective factor is determined by linear interpolation.

If both performance criteria are met, on expiry of the performance period a minimum of 2% and a maximum of 8% of the annual fixed salary as of 1 October 2008 is paid out if there is a personal investment of 100 shares.

In addition to the members of the Board of Management, a further 104 employees participate in the Long Term Incentive Programme with a total personal investment of 22,500 preference shares. 5,450 preference shares where virtually allocated to employees of Biotest Pharmaceuticals Corp.

The valuation was carried out by external consultants (Towers Perrin, Frankfurt/Main), using the Monte Carlo simulation. In the valuation of market conditions as well as non-market conditions pursuant to IFRS 2 "Share-based Payment", conditions which affect the incentive payment but are not observable in the market are separated from observable market conditions. The determination of market conditions is undertaken by means of a fair value assessment. As of 31 December 2008, the fair value determining the granting of an incentive payment relating to the outperformance of the SDAX peer group amounted to €3.488 per 100 preference shares in the equity and €100 fixed payment. As of the time of granting the incentive payment on 1 May 2008, the fair value amounted to €2.484. Non-market conditions are taken into account through the addition of performance factor 2, determined on the basis of budget forecasts. The sum of the factors as of 31 December 2008 amounted to 5.483 %.

All market parameters that are not directly observable are obtained through statistical estimates. Historical market data is used in the valuation to factor in volatility. The risk free market interest rate to be used is determined on the basis of the Svensson method parameters published by Deutsche Bundesbank. To determine the number of people likely to leave the programme during the term, a staff turnover rate of 4% was assumed for the beneficiaries.

The total expense up to 2010 is expected to amount to  $\leq$ 1,939 thousand on the basis of 31 December 2008.

As a provision as of 31 December 2008, a pro rata value of  $\in$ 485 thousand was stated in line with the distribution over the full term up to 31 December 2010.

#### Long Term Incentive Programme/2007 tranche

The 2007 tranche of the Long Term Incentive Programme was described in detail in the annual report for the previous year.

Performance factor 1 of the 2007 tranche is identical to the 2006 and 2008 tranche, as shown below:

Position vs. benchmark (shares SDAX)	Performance factor 1
Better than 3 <sup>rd</sup> quartile	0.04
Same as median	0.02
Better than 1 <sup>st</sup> quartile	0.01
Worse/same as 1 <sup>st</sup> quartile	0.00

Performance factor 2 of the 2007 tranche has slightly different intervals compared with the 2006 and 2008 tranche, as follows:

Average EBIT marge 2007–2009	Performance factor 2
16.5% an higher	0.04
Equal to 13.0%	0.02
At least 10.0%	0.01
Below 10.0%	0.00

The level of the incentive payment is calculated in accordance with the following formula:

own investment x performance factor 1	
+ own investment x performance factor 2	annual fixed salary x as of 1 October 2007
100	as of 1 October 2007

Up to 2009, total costs of €1,345 thousand are expected on the basis of 31 December 2008.

The valuation of the 2007 tranche was recognised as a provision amounting to €215 thousand in the balance sheet as of 31 December 2007.

In 2008, the year-end value as of 31 December 2008 was increased to €807 thousand. Costs for the period totalled €582 thousand in 2008.

The total of the factors as of 31 December 2008 changed from 4.468% to 5.635%. Following departures from the company and deinvestment, the number of beneficiaries decreased by one person. Personal investment in preference shares was reduced by a total of 800 shares.

#### Long Term Incentive Programme/2006 tranche

The 2006 tranche of the Long Term Incentive Programme was described in detail in the annual report to 31 December 2006.

Performance factor 1 of the 2006 tranche is identical to the 2007 and 2008 tranche, as shown below:

Position vs. benchmark (shares SDAX)	Performance factor 1
Better than 3 <sup>rd</sup> quartile	0.04
Same as median	0.02
Better than 1 <sup>st</sup> quartile	0.01
Worse/same as 1 <sup>st</sup> quartile	0.00

Performance factor 2 of the 2006 tranche has slightly different intervals compared with the 2007 and 2008 tranche, as follows:

Average EBIT marge 2006–2008	Performance factor 2
16.0% and higher	0.04
Equal to 12.5%	0.02
At least 9.1%	0.01
Below 9.1%	0.00

The level of the incentive payment is calculated in accordance with the following formula:

own investment x performance factor 1 + own investment x performance factor 2

annual fixed salary 100 x as of 1 October 2006 = payment

Under IFRS 2, the balance sheet valuation of the 2006 tranche is treated as continuation of the 2005 programme with amended parameters. In the continuation of the programme from 2005, the valuation in the balance sheets as of 31 December 2006, 2007 and 2008 therefore follows on from the value as derived at the time of the Annual Shareholders' Meeting in May 2006. In 2006, this amount was increased to the yearend value of €490 thousand. The period expense totalled €355 thousand.

In 2007, the year-end value as of 31 December 2007 was increased to €775 thousand. The period expense amounted to €285 thousand in 2007.

In 2008, the year-end value as of 31 December 2008 was increased to €1,236 thousand. The period expense amounted to €461 thousand in 2008. The total of the factors as of 31 December 2008 changed from 4.907% to 5.884%. On balance sheet date the number of participants of the 2006 tranche was 59 employees whose investment in preference shares was a total of 16,310. The 2006 tranche is to be paid out in May 2009.

Entitlement to incentive payments lapses for all three tranches if employment with the Biotest Group ends, regardless of the reason (except in the case of retirement, early retirement, partial retirement and incapacity to work).

Participants receive a pro rata incentive payment in the event of a change of control if a minimum of 30% of the voting rights are transferred to a shareholder who was not previously in a position to exercise these voting rights, in the event of delisting from the official market, in the event of a merger or change in the legal form of the parent company, or in the event of the company by which the participant is employed leaving the scope of consolidation of the parent company.

# F2 Financial instruments

### F2.1 Reconciliation of classification in valuation categories and the values stated and fair values

€ thousand			Value state	Value stated in the balance sheet according to IAS 39					
Balance sheet items (classification)	Valuation category according to IAS 39	Book value as of 31 Dec 2008	Amortised cost of purchase	Cost of purchase	Fair value recognised in equity	Fair value recognised in profit or loss	Valuation in the balance sheet according to IAS 17	Fair value as of 31 Dec 2008	
Assets									
Trade receivables	LaR	94,481	94,481	-	-	-	-	94,481	
Other receivables	LaR	20,186	20,186	-	-	-	-	20,186	
Other primary financial asset	ts								
Bond funds	FAFVtPL	136	-	-	-	136	-	136	
Fixed-income securities	HtM	87	87	-	-	-	-	87	
Loans to employees	LaR	14	14	-	-	-	-	14	
Derivative financial assets									
Derivatives without hedging relationships	FAHfT	279	_	_	_	279	_	279	
Equity and liabilities									
Trade payables	FLAC	48,730	48,730	_	-	-	_	48,730	
Collateralised bank liabilities	FLAC	162,118	162,118	_	_	_	_	162,118	
Unsecured bank liabilities	FLAC	19,047	19,047	_	_	-	_	19,468	
Other non-interest bearing liabilities	FLAC	4,209	4,209	_	_	-	_	4,209	
Liabilities from finance leases	n.a.	9,466	-	_	_	-	9,466	9,466	
Other unsecured loans	FLAC	17,154	17,154	_	-	-	_	17,154	
Derivatives without hedging relationship	FLHfT	135	_	_	_	135	_	135	

		Value state	ed in the bala	nce sheet accord			
Valuation category according to IAS 39	Book value as of 31 Dec 2007	Amortised cost of purchase	Cost of purchase	Fair value recognised in equity	Fair value recognised in profit or loss	Valuation in the balance sheet according to IAS 17	Fair value as of 31 Dec 2007
L - D	101 141	101 1 41					101 1 41
LaR	101,141	101,141	_	_		_	101,141
LaR	14,326	14,326	_			_	14,326
FAFVtPL	130			_	130		130
HtM	111	111	_	_	_	_	111
LaR	17	17	-	-	_	-	17
FAHfT	414	_	_	_	414		414
FLAC	32,117	32,117	_	_	-	-	32,117
FLAC	155,384	155,384	_	-	-	-	155,384
FLAC	15,151	15,151	_	-	_	-	14,986
FLAC	16,955	16,955	_	_	_	-	16,955
n.a.	14,222	_	_	_	_	14,222	14,222
FLAC	4,002	4,002	_	_	_	-	4,002
FLHfT	38	_	_	_	38	-	38

The valuation categories according to IAS 39 are abbreviated as follows: Loans and Receivables (LaR), Investments Held to Maturity (HtM), Financial Assets at Fair Value through Profit or Loss (FAFVtPL), Financial Assets Held for Trading (FAHfT), Financial Liabilities Held for Trading (FLHfT) and Financial Liabilities at Amortised Cost (FLAC).

Cash and cash equivalents with a book value of €8,072 thousand (2007: €8,889 thousand) are not included in the table above, since these financial instruments are not allocated to any of the IAS 39 valuation categories.

#### F2.2 Aggregation of the valuation categories including values stated and fair values

€ thousand		Value stated in the balance sheet according to IAS 39							
Category	Valuation category according to IAS 39	Book value as of 31 Dec 2008	Amortised cost of purchase	Cost of purchase	Fair value recognised in equity	Fair value recognised in profit or loss	balance sheet according	Fair value	
Loans and accounts receivable	LaR	114,681	114,681	-	_	-	_	114,681	
Investments held to maturity	HtM	87	87	-	-	-	_	87	
Financial assets at fair value through profit or loss	FAFVtPL	136	_	_	_	136	_	136	
Financial assets held for trading	FAHfT	279	-	_	-	279	_	279	
Financial liabilities measured at amortised cost	FLAC	251,258	251,258	_	_	_	_	251,619	
Financial liabilities held for trading	FLHfT	135	-	-	-	135	_	135	

		Value-stat	ed in the bala	nce sheet accor	ding to IAS 39				
Valuation category according to IAS 39	Book value as of 31 Dec 2007	Amortised cost of purchase	Cost of purchase	Fair value recognised in equity	Fair value recognised in profit or loss	Valuation in the balance sheet according to IAS 17	Fair value as of 31 Dec 2007		
LaR	115,484	115,484	-	_	_	_	115,484		
HtM	111	111	-	_	_	_	111		
FAFVtPL	130	-	_	-	130	-	130		
FAHfT	414	-	_	_	414	-	414		
FLAC	223,609	223,609	_	-	-	_	223,444		
FLHfT	38	_	-	-	38	_	38		

Trade receivables and other accounts receivable primarily have a time to maturity of less than one year. For this reason, the book values as of the reporting date correspond approximately to the fair values.

With regard to other non-current accounts receivable and investments held to maturity, which have a time to maturity of more than one year, the fair values correspond to the present values of the payments relating to the assets. The applicable interest rate parameters are taken into account in each case, which reflect market and partnerspecific changes in terms and expectations.

Trade payables and other liabilities generally have a time to maturity of less than one year. Accordingly, the book values correspond approximately to the respective fair values.

The fair values of liabilities to banks and other financial liabilities are determined as the present values of the payments relating to the debt, based on the applicable yield curve in each case and the credit spread curve analysed for each currency.

As of 31 December 2008, the Biotest Group had no investment categorised as available-for-sale in its portfolio.

### F 2.3 Net results by valuation categories

In the following, the net result for the previous year is shown by valuation category:

€ thousand	From interest	From subsequent valuation			From disposal	Net result for 2008
Category		At fair value	Currency translation	Allowance		
Loans and receivables	972	-	145	-194	-	923
Investments held to maturity	5	_	_	_	_	5
Financial assets at fair value through profit or loss	25	2	_	_	_	27
Financial assets held for trading	_	-403	_	_	_	- 403
Financial liabilities held for trading	_	- 127	_	_	_	- 127
Financial liabilities measured at amortised cost	-12,539	_	_	_	_	- 12,539
Total	-11,537	-528	145	- 194	-	- 12,114

€ thousand	From interest	From subsequent valuation			From disposal	Net result for 2007
Category		At fair value	Currency translation	Allowance		
Loans and accounts receivable	474	-	- 24	- 34	-	416
Investments held to maturity	4	_	_	-	_	4
Financial assets at fair value through profit or loss	21	-10	_	_	_	11
Financial assets held for trading	_	216	_	_	_	216
Financial liabilities held for trading	_	324	_	_	_	324
Financial liabilities measured at amortised cost	- 7,189	_	_	_	_	- 7,189
Total	- 6,690	530	- 24	- 34	-	- 6,218

### In the following, the net result for the previous year is shown by valuation category:

The other components comprised in the net result are included in other financial expenses and other financial income, with the exception of allowances on trade receivables which are reported under other operating expenses.

The result from the subsequent valuation of financial instruments allocated to the financial assets and liabilities held for trading categories comprises a profit amounting to €530 thousand (2007: €540 thousand), which takes account of interest rate and currency effects.

#### F 2.4 Cash flow in periods

The table below shows the contractually agreed, non-discounted interest and amortisation payments relating to the primary financial liabilities and derivative financial instruments, with the positive and negative fair values:

		Ca	ash flow in 20	09		Cash flow in 201	10	
€ thousand	Book value as of 31 Dec 2008	Fixed interest rate	Floating interest rate	Amorti- sation	Fixed interest rate	Floating interest rate	Amorti- sation	
Primary financial liabilities:								
Liabilities to banks	- 181,165	- 934	- 7,416	- 18,710	- 762	- 7,064	-13,379	
Liabilities from finance leases	- 9,466	- 628	-	- 5,688	- 259	-	- 2,946	
Other interest-bearing liabilities	-4,209	- 28	_	- 3,793	- 19	-	-13	
Other non-interest bearing liabilities	- 17,154	_	_	- 16,934	_	_	- 75	
Derivative financial liabilities:								
Currency derivatives without hedging relationship	_	_	_	_	_	_	-	
Interest rate derivatives without hedging relationship	-135	-	-12	_	-	-10	-	
Derivative financial assets:								
Currency derivatives without hedging relationship	-	_	_	_	_	_	_	
Interest rate derivatives without hedging relationship	279	_	- 6	_	_	- 6	_	

All instruments in the portfolio as of 31 December 2008, for which payments were already contractually agreed, have been included above. Forecast figures for future new liabilities are not included. Foreign currency amounts have been translated at the exchange rate applicable on the reporting date. The floating interest rate payments for financial instruments are determined on the basis of the latest interest rates set prior to 31 December 2008. Financial liabilities repayable at any time are always allocated to the earliest date occurring.

	Cash flow in 2011		Cash flow in 2012			Cash flow in 2013			Cash flow after 2013		
Fixe intere ra	st interest	Amorti-	Fixed interest rate	Floating interest rate	Amorti- sation	Fixed interest rate	Floating interest rate	Amorti- sation	Fixed interest rate	Floating interest rate	Amorti- sation
- 63	2 - 6,581	- 22,939	- 556	- 5,675	- 32,418	-481	- 4,065	- 28,869	- 570	- 5,308	-66,184
- 3	6 –	- 333	-21	-	-234	- 9	-	-179	- 2	-	- 86
- 1	.9 –	-14	-18	-	-14	-17	-	-15	-127	-	- 360
		-11	-	-	-11	_	_	-11	-	-	-114
		_	-	_	_	_	_	_	-	_	-
	5	_	_	_	_	_	_	_	_	_	-
		_	_	_	_	_	_	_	_	_	-
	6	_	_	- 5	-	_	- 5	_	_	- 5	-

The following table provides the comparative values for the cash flow in specific periods of time, based on the previous financial year:

€ thousand		Ca	ash flow in 20	08		Cash flow in 2009		
	Book value as of 31 Dec 2007	Fixed interest rate	Floating interest rate	Amorti- sation	Fixed interest rate	Floating interest rate	Amorti- sation	
Primary financial liabilities:								
Liabilities to banks	- 170,535	-4,368	- 6,021	- 16,985	- 4,280	- 5,337	- 7,191	
Liabilities from finance leases	- 14,222	- 844	-	- 5,460	- 585	_	- 5,567	
Other interest-bearing liabilities	- 4,002	- 46	- 155	- 3,624	- 20	_	-12	
Other non-interest bearing liabilities	- 16,955	-	-	- 16,955	-	-	-	
Derivative financial liabilities:								_
Currency derivatives without hedging relationship	-9	_	_	- 9	_	_	_	
Interest rate derivatives without hedging relationship	- 29	- 21	_	_	_	_	_	
Derivative financial assets:								
Currency derivatives without hedging relationship	79	_	_	79	_	_	_	
Interest rate derivatives without hedging relationship	335	_	282	_	_	183	-	

## F3 Financial risk management

In the course of its ordinary operations and due to existing international delivery and service relations, Biotest is exposed to substantial currency and interest rate risks.

To hedge currency and interest rate positions, Biotest uses derivative financial instruments in order to minimise risk inherent in exchange rate and interest rate fluctuations. Derivative financial instruments are as a general rule subject to changes in market prices.

	Cash flow in 2010		Cash flow in 2011		Cash flow in 2012			Cash flow after 2012				
inte	ixed rest rate	Floating interest rate	Amorti- sation	Fixed interest rate	Floating interest rate	Amorti- sation	Fixed interest rate	Floating interest rate	Amorti- sation	Fixed interest rate	Floating interest rate	Amorti- sation
- 4	,001	- 5,189	- 11,398	- 3,506	- 5,156	- 19,704	- 2,576	- 4,644	- 29,189	- 2,423	- 9,655	- 87,620
-	228	-	-2,818	- 15	-	- 197	- 7	-	-103	- 2	-	- 77
	- 19	_	-13	-19	_	-14	-18	_	-14	-144	-	- 325
	_	_	_	_	_	_	_	_	_	_	_	_
	_	_	_	_	_	_	_	_	_	_	_	_
	_	-	_	_	-	_	_	-	_	-	-	-
	_	_	_	_	_	_	_	_	_	_	_	_
	_	107	_	_	68	-	_	36	-	_	89	_

Currently, Biotest does not comply with all formal requirements of IAS 39 for hedge accounting. Consequently, all gains and losses, recorded when derivative financial instruments used to hedge interest rate and currency risks are marked to market, have been accounted for in the income statement.

Financial instruments are recognised when the corresponding contracts are entered into. Financial instruments are initially accounted for at cost and then valued at the corresponding market values as of the balance sheet date. Financial instruments are derecognised when the obligations under the contract have been fulfilled by both parties or when the positions in such instruments are closed.

The market values of derivative financial instruments are shown in the balance sheet under other assets and other provisions respectively. As of 31 December 2008, an amount of  $\notin$  279 thousand (2007:  $\notin$  414 thousand) was reported under other assets and of  $\notin$  135 thousand (2007:  $\notin$  38 thousand) under other provisions.

#### **Credit risks**

Credit risks represent the financial risk of contractual parties not fulfilling their payment obligations. Biotest responds to credit risks with ongoing management of accounts receivable. Credit terms and other terms are based on the rating of the customers' creditworthiness. Moreover, part of the German accounts receivable and selected foreign accounts receivable are sold to factoring companies or banks.

As of the reporting date, there were no significant customer groups representing a particular credit risk.

For some customers in selected countries, credit insurance is in place with various companies.

Specific bad debt charges are in place for potential default risks relating to primary financial instruments. Thanks to its broadly diversified business structure, the Biotest Group does not face any concentration of credit risks with regard to individual customers or countries.

Overview of the maximum default risk relating to financial assets:

	Trade re	eceivables	Financial assets		
€ thousand	2008	2007	2008	2007	
Book value as equivalent of the maximum default risk	94,481	101,141	237	258	

#### Market risks

Market price risks arise from changes in market prices. These result in fluctuations in the fair values or future cash flows relating to the financial instruments. Market risks comprise foreign exchange risks, interest rate risks and other price-related risks.

#### Foreign currency risks

The Biotest Group is exposed to currency risks that mainly arise from an imbalance in the global cash flow. This imbalance primarily results from higher sales in US dollars in the face of lower purchases in US dollars. The Biotest Group protects itself as a matter of principle against identifiable future currency risks when it anticipates such exposure. In addition, the Biotest Group selectively hedges risks in the balance sheet. The Biotest Group utilises opportunities to naturally offset currency risks, as well as currency futures for the management of foreign currency risks.

### The Biotest Group holds the following positions in the foreign currencies that are material to the Group:

		USD		GBP		HUF		
€ thousand	2008	2007	2008	2007	2008	2007		
Cash reserve	2,792	919	113	649	14	383		
Trade receivables	13,532	13,586	906	1,592	1,520	2,570		
Other primary financial assets	_	2,538	-	94	-	272		
Other derivative financial assets	_	78	-	_	-	_		
Trade payables	-11,476	- 3,063	- 276	- 60	- 51	- 898		
Liabilities to banks	- 62,358	- 61,998	-	- 3	-	_		
Other primary financial liabilities	- 3,843	- 2,491	- 71	- 361	- 346	- 157		
Other derivative financial liabilities	-	_	-	-	-	- 9		
Net exposure	- 61,353	- 50,431	672	1,911	1,137	2,161		

As of the reporting date, the following currency options were in place:

	Nominal	volume	Market values		
€ thousand	2008	2007	2008	2007	
Currency options	-	2,305	-	69	

As of the balance sheet date 2007, the remaining times to maturity for currency options and currency futures (nominal volumes USD 2,000 thousand and HUF 240,000 thousand) were as follows:

		Time to maturity
€ thousand	Total	< 1 year
31 December 2008	-	-
31 December 2007	2,305	2.305

Section B3 provides information about the material exchange rates during the reporting period.

#### Interest rate risk

As a result of changes in the yield curve, the present values of payment flows change when discount rates change. The change in present value may arise for individual financial instruments on the basis of a shift in the risk-free interest rate curve (swap curve) or a change in the credit-based premiums (spread risks) which are included in the prices of the financial instruments.

The Biotest Group is exposed to interest rate risks resulting form existing loans (see also section E14 Financial liabilities). Interest rate hedging instruments were entered into to minimise such risks.

	Nom	inal volume	Market volume		
€ thousand	2008	2007	2008	2007	
Interest rate caps	65,000	45,113	137	84	
Interest rate/currency swaps	4,203	10,685	8	222	
	69,203	55,798	145	306	

The following interest rate hedging transactions were in place as of 31 December:

The nominal volume is the sum of all purchase and sale prices of derivative financial transactions. The market values of the interest rate hedging instruments were determined by the banks appointed for this purpose. They result from the valuation of outstanding positions at market prices, without taking into account contrary performance by underlying transactions. They correspond to expenses or income for liquidation of the derivative contracts on the balance sheet date.

The following times to maturity were in place for hedging transactions (nominal volume) as of 31 December:

			Time to matur	ity
€ thousand	Total	< 1 year	1–5 years	> 5 years
2008				
Interest rate caps	65,000	30,000	10,000	25,000
Interest rate/currency swaps	4,203	-	1,563	2,640
	69,203	30,000	11,563	27,640
2007				
Interest rate caps	45,113	5,113	40,000	-
Interest rate/currency swaps	10,685	5,113	2,812	2,760
	55,798	10,226	42,812	2,760

To hedge against interest rate risks, floating rate financial liabilities amounting to  $\notin$ 4.2 million (2007:  $\notin$ 5.6 million) were swapped for fixed-interest positions. Interest in a range of 3.17% to 3.67% was paid on fixed-rate financial liabilities.

Under the interest rate caps, financial liabilities with a volume of €45.0 million (2007: €25.1 million) are also secured against an increase in variable interest rates via agreed threshold values of between 3.5% and 5.0%.

### Liquidity risks

Liquidity risks reflect the risk that companies are unable to fulfil their financial obligations to a sufficient extent. A financial squeeze may result in an increase in financing costs.

The Biotest Group manages its liquidity by maintaining sufficient liquid funds and credit lines with banks in addition to its cash inflow.

€ thousand	2008	thereof drawn on	2007	thereof drawn on
Credit lines extended (with option to draw on without restruction)	239,720	182,029	220,078	172,820
Firm credit commitments (contingent on specific conditions)	14,800	3,344	14,800	1,717
	254,520	185,373	234,878	174,537

As of 31 December 2008, the Biotest Group had access to the following credit lines:

The individual corporate segments supply central Treasury with information, so that a liquidity profile can be prepared. All financial assets, financial liabilities and expected payment flows from planned transactions are included.

A maturity overview is provided in section F2.4, which illustrates how the cash flows of liabilities as of 31 December 2008 impacted on the liquidity position of the Group.

The available liquidity, short and long-term credit lines and the option of generating cash inflows by securitising accounts receivable provide the Biotest Group with sufficient flexibility to cover the Group's funding requirement. Given the diversification of the funding sources and liquid funds, the Biotest Group is not exposed to a concentration of risk in terms of liquidity.

### F4 Sensitivity analysis pursuant to IFRS 7.40

The Biotest Group is exposed to market risks, comprising currency risks and interest rate risks.

Using sensitivity analyses, the effects of any change in the relevant risk variables on profit or loss and on equity as of the balance sheet date are determined for each type of risk.

### Foreign currency risks

For the analysis of currency risks, a sensitivity analysis is prepared for specific currencies that imply a significant risk to the Biotest Group. The following important currencies are analysed: USD, GBP and HUF.

Had the euro been revalued by 10% against all of the currencies as of 31 December 2008, operating profit would have been €272 thousand higher (2007: €151 thousand lower).

Had the euro been devalued by 10% against all of the currencies as of 31 December 2008, operating profit would have been €339 thousand lower (2007: €179 thousand higher).

In both cases, the financial result and equity would have remained unchanged.

In detail, the hypothetical impact on profit or loss of €272 thousand and €–339 thousand respectively results from the currency sensitivities:

€ thousand	Revaluation of the euro by 10%	Devaluation of the euro by 10%
EUR/USD	114	- 77
EUR/GBP	7	- 9
EUR/HUF	87	- 175
EUR/other currencies	64	- 78
	272	- 339

Since intercompany relationships are not included in the calculation of currency sensitivities under the regulations of IFRS 7, but these represent a material payment flow for the Biotest Group, the currency effects presented here do not correspond to the relationship between hedging transactions and underlying transactions.

#### Interest rate risks

For interest rate risks, a sensitivity analysis is used to illustrate the effects of changes in market interest rates on the interest income and expense, other income components and, where applicable, equity.

Changes in the market interest rates of primary financial instruments with fixed interest rates only impact on income if they are valued at fair value. Accordingly, all financial instruments with fixed interest rates which are valued at amortised cost are not exposed to interest rate risks pursuant to IFRS 7.

Changes in the market interest rates of interest rate derivatives (interest rate swaps, interest rate/currency swaps), which are not included in a hedging relationship under IAS 39, impact on other financial income (valuation result of the financial assets adjusted to fair value) and are therefore taken into account in the income-related sensitivity calculations.

Currency derivatives are not subject to interest rate risks and do not therefore impact on interest rate sensitivities.

If the market interest rate level as of 31 December 2008 had been 100 basis points higher, the fair values of the financial instruments would have been  $\leq 1,003$  thousand higher (2007:  $\leq 946$  thousand). The hypothetical effect on income of  $\leq 466$  thousand (2007:  $\leq 327$  thousand) results from the potential effects of interest rate derivatives amounting to  $\leq 466$  thousand (2007:  $\leq 327$  thousand) and primary financial liabilities of  $\leq 0$  thousand (2007:  $\leq 0$  thousand).

If the market interest rate level as of 31 December 2008 had been 100 basis points lower, the fair values of the financial instruments would have been  $\in$ 789 thousand lower (2007:  $\in$ 1,073 thousand). The hypothetical effect on income of  $\in$ -225 thousand (2007:  $\in$ -421 thousand) results from the potential effects of interest rate derivatives amounting to  $\in$ -225 thousand (2007:  $\in$ -421 thousand) and primary financial liabilities of  $\in$ 0 thousand (2007:  $\in$ 0 thousand).

If the market interest rate level as of 31 December 2007 had been 100 basis points higher (lower), equity would have remained unchanged.

### Other price-related risks

As part of the presentation of market risks, IFRS 7 also requires information about how hypothetical changes in risk variables affect the prices of financial instruments. Possible risk variables are in particular stock exchange prices and indices.

Other price-related risks have no material impact on the prices of the financial instruments held by the Biotest Group.

## **F5** Contingencies

€ thousand	2008	2007
Guarantees	5,634	-
Other contingent liabilities	-	-
	5,634	-

Contingent liabilities are potential obligations which result from past events and whose existence has to be confirmed by the occurrence or non-occurrence of one or more uncertain future events, which are not within the full control of the company. Contingent liabilities can also stem from current obligations resulting from past events, which however, are not recorded because either the outflow of resources plus losses of financial benefit is not probable or the amount of the obligation cannot be estimated with sufficient reliability.

### F6 Other financial commitments

€ thousand	in 2009	2010–2013	from 2014	Total
Commitments to purchase property, plant and equipment	8,140	_	_	8,140
Commitments to purchase intangible assets	196	_	_	196
Commitments resulting from long-term service				
contracts	4,893	22,612	49,995	77,500
Other purchase commitments	5,530	-	-	5,530
Future payments from rent and lease agreements, and				
operating leases	4,817	8,074	2,049	14,940
Other financial commitments	50	_	_	50
	23,626	30,686	52,044	106,356

Payments for the approved investment in fixed assets will be made within one year.

The obligations under long-term service agreements relate to purchase commitments under a toll manufacturing agreement for the period from 2009 to 2018 amounting to €77,500 thousand.

Biotest rents and leases operating equipment. Operating leases include vehicle and office equipment with a base rental term of two to five years. In financial year 2008, expenditure on rental and operating lease contracts amounted to €5,836 thousand (2007: €3,897 thousand).

# F7 Related party relationships

Disclosure is required for the Biotest Group's relationship with the associated company BioDarou P.J.S. Co. Teheran/Iran and members of the Board of Management and the Supervisory Board and their related persons.

### a) Associated companies

In financial year 2008, the Biotest Group recorded purchases amounting to €0 thousand (2007: €0 thousand) from the associate BioDarou P.J.S. Co. in Teheran/Iran. Liabilities of the Group to BioDarou P.J.S. Co. amounted to €0 thousand (2007: €0 thousand) as of the balance sheet date.

The company purchased goods and services from Biotest Group companies amounting to  $\leq 1,216$  thousand (2007:  $\leq 880$  thousand). Liabilities resulting out of this where at  $\leq 1,107$  thousand at balance sheet date (2007:  $\leq 0$ ).

### b) Other related parties

Dr. Cathrin Schleussner advised the Biotest Group that her voting rights totalled 50.03% as of 19 December 2007. The voting rights are held via OGEL GmbH, Frankfurt/ Main. OGEL GmbH is controlled by Dr. Cathrin Schleussner.

The members of the Dr. Hans Schleussner family are also deemed related persons for the purposes of IAS 24. Expenses for other related persons of the Schleussner family amounted to  $\leq 18$  thousand (2007:  $\leq 21$  thousand). Shareholder loans resulted in interest expenses of  $\leq 0$  thousand in 2007 and 2008.

As a related party of the Biotest Group, Kreissparkasse Biberach maintains the custody accounts of employees as part of the Long Term Incentive Programme.

In 2007, the law firm Ashurst received €287 thousand for advisory services as a related party. In 2008, Ashurst was no longer seen as related party.

### c) Supervisory Board and Board of Management

#### **Board members**

As of 31 December 2008, the members of the Supervisory Board and the Board of Management additionally served on statutory Supervisory Boards and comparable control boards of commercial enterprises as follows:

### Supervisory Board

Dr. Thorlef Spickschen, businessman, Seeheim Chairman Stiftung Orthopädische Universitätsklinik, Heidelberg, Germany Cytos AG, Zurich, Switzerland

Dr. Cathrin Schleussner, biologist, Neu-Isenburg Deputy Chairwoman

Dr. Marbod Muff, economist, Ingelheim

Thomas Jakob, businessman, Warthausen Deputy Chairman of the Management Board of Kreissparkasse Biberach

Barbara Arnold-Schlosser, employee – administration, Leimen

Astrid Paluch, employee – technology, Rödermark

€ thousand 2008	Fixed remuneration	Variable remuneration	Total remuneration
Dr. Thorlef Spickschen (Chairman)	43	5	48
Dr. Cathrin Schleussner (Deputy Chairwoman)	29	5	34
Prof. Dr. Marbod Muff (since September 2008)	6	2	8
Dr. Jochen Hückmann (until May 2008)	9	2	11
Thomas Jakob	18	5	23
Barbara Arnold-Schlosser	18	5	23
Astrid Paluch	15	5	20
	138	29	167

€ thousand 2007	Fixed remuneration	Variable remuneration	Total remuneration
Dr. Thorlef Spickschen (Chairman)	43	5	48
Dr. Cathrin Schleussner (Deputy Chairwoman)	29	5	34
Dr. Jochen Hückmann	23	5	28
Thomas Jakob (since May 2007)	12	3	15
Barbara Arnold-Schlosser (since May 2007	) 12	3	15
Astrid Paluch (since May 2007)	10	3	13
Kerstin Birkhahn (until May 2007)	5	2	7
Reinhard Eyring (until May 2007)	6	2	8
Johannes Hartmann (since May 2007)	6	2	8
	146	30	176

### **Board of Management**

Prof. Dr. Gregor Schulz, physician, Umkirch Chairman

Dr. rer. pol. Michael Ramroth, lawyer, Mörfelden-Walldorf Member of the Board of Management

Total remuneration for the members of the Board of Management who actively served in 2008 amounted to €908 thousand (2007: €1,126 thousand).

Of this, fixed remuneration in the amount of €300 thousand relates to Professor Dr. Gregor Schulz, plus allowances, for example, for insurance policies and benefits in kind for a company car in the total amount of €35 thousand. A provision of €150 thousand was recognised for performance-related remuneration.

€260 thousand of the total relates to fixed remuneration for Dr. Michael Ramroth, plus allowances, for example, for insurance policies and benefits in kind for a company car totalling €32 thousand. A provision of €130 thousand was recognised for performance-related remuneration.

The employment contracts of both members of the Board of Management include a severance regulation in the event that the contracts are prematurely terminated as a result of a change of control defined below. The severance payment comprises the fixed remuneration until the end of the term plus pro rata bonuses calculated on the basis of the average amount of the last two financial years plus remuneration for the value in use of the company car. If the remaining term is less than three years, the severance payment amounts to triple the annual fixed remuneration plus bonuses and company car remuneration. The entitlement does not arise if the Board of Management employment contract is terminated early for good cause, illness or incapacity to work or if the member of the Board of Management was already aged 60 respective 62 when the contract was terminated or received incentives or advantages from third parties in conjunction with the change of control.

There are no other one-off or recurring commitments in the event of a termination of the Board of Management position.

Participation of the members of the Board of Management in the Long Term Incentive Programme (2006, 2007 and 2008 tranches) breaks down as follows:

€ thousand	Value of shares purchased	Company allowance for own investment	Total costs of the stock option plan	Cost of the stock option plan in the financial year
2008				
Prof. Dr. Gregor Schulz	23	-	494	163
Dr. Michael Ramroth	23	-	442	145
	46	-	936	308
2007				
Prof. Dr. Gregor Schulz	23	_	268	70
Dr. Michael Ramroth	23	-	244	63
	46	-	512	133

Pension provisions in the amount of €1,543 thousand (2007: €1,348 thousand) were recognised for the active members of the Board of Management. Of these, €1,137 thousand (2007: €984 thousand) are attributable to Professor Dr. Gregor Schulz and €406 thousand (2007: €364 thousand) to Dr. Michael Ramroth.

Provisions of €3,781 thousand (2007: €4,172 thousand) were recognised for pension obligations to former members of the Board of Management. As of the balance sheet date, there were no loan claims against any members of the company's management bodies.

Pension payments to former members of the Board of Management amounted to €385 thousand (2007: €385 thousand).

# F8 Material subsidiaries

The following subsidiaries were fully consolidated in the financial statements of the Biotest Group.

		Interest held	Shareholders' equity	Profit after tax
Company name	Registered office	in %	€ million	€ million
Biotest Pharma GmbH	Dreieich/Germany	100.00	93.4	6.9
Biotest Grundstücksverwaltungs GmbH	Dreieich/Germany	98.00	3.2	0.4
Biotest Seralc° N.V.	Mechelen/Belgium	100.00	0.5	-0.1
Biotest S.a.r.l.	Paris/France	100.00	1.4	0.3
Biotest (UK) Ltd.	Manchester/UK	100.00	1.7	0.5
Biotest Italia S.r.l.	Milano/Italy	100.00	9.3	0.3
Biotest K.K.	Yokohama/Japan	100.00	0.0	0.1
Biotest Austria GmbH	Vienna/Austria	100.00	2.2	0.4
Biotest (Schweiz) AG	Rupperswil/Switzerland	100.00	1.5	0.5
Biotest Hungaria Kft.	Budapest/Hungary	100.00	2.8	0.4
Biotest Diagnostics Corporation	Rockaway/USA	100.00	0.8	- 0.9
Biotest Hellas MEPE	Athens/Greece	100.00	3.4	0.0
heipha Dr. Müller GmbH	Eppelheim/Germany	51.00	8.9	4.8
Viro-Immun Labor-Diagnostika GmbH	Oberursel/Germany	89.975	0.4	0.0
Biotest Medical Diagnostics GmbH	Dreieich/Germany	100.00	12.0	- 1.2
Plasmadienst Tirol GmbH	Innsbruck/Austria	100.00	0.4	0.0
Plasma Service Europe GmbH *	Dreieich/Germany	100.00	0.4	0.0
Biotest Pharmaceutical Corporation	Boca Raton/USA	100.00	72.7	2.5
Biotest US Corporation	Boca Raton/USA	100.00	71.9	0.0
Plazmaszolgálat Kft.	Budapest/Hungary	100.00	0.2	-0.1

\* Plasma Service Europe GmbH and Biotest Pharma GmbH entered into a profit transfer agreement.

# F9 Pending and imminent litigation

As of the balance sheet date, provisions amounting to  $\leq$ 400 thousand (2007:  $\leq$ 795 thousand) were recognised for litigation pending.

## F10 Events after the balance sheet date

No events occurred after the balance sheet date, which would have significantly influenced the earnings, financial and assets position of the company.

### F11 Exercise of discretion and uncertainty of estimates

When preparing the consolidated financial statements, to a certain degree assumptions and estimates have to be made, which have an effect on the amount and disclosure of the reported assets and liabilities as well as the income and expenses during the period under review. The assumptions and estimates for the most part relate to the recoverability of accounts receivable and inventories and the assessment of the probabilities of occurrence with regard to the potential requirement to recognise provisions. In evaluating these assumptions and estimates, the management relies on experience from the past, assessments of experts (lawyers, rating agencies, and trade associations) and the result of carefully weighing up different scenarios. Due to developments that deviate from these assumptions and that are beyond the control of the management, the actual amounts may differ from the initially expected estimated values. In the cases where the actual development deviates from the initially expected development, the premise and, where necessary, the book values of the assets and liabilities concerned are adjusted accordingly.

At the time of preparing the financial statements, the underlying assumptions and estimates were subject to considerable uncertainty regarding the future development of the economy and the financial industry. The current excess demand for Plasma and Plasma Proteins products could also reduce more quickly and extensively than previously assumed as a result of the worsening economic situation and cuts in the health budget, and even lead to a surplus supply of Plasma and Plasma Proteins products, which could lead to significant price falls. There is therefore a high level of uncertainty regarding future risks. Consequently, from today's perspective, it cannot be ruled out for the following financial year that adjustments may have to be made to the book values of assets and liabilities stated in the balance sheet.

### F12 Corporate Governance

The Board of Management and the Supervisory Board of Biotest AG submitted the declaration of compliance required pursuant to Section 161 of the German Stock Corporation Act (AktG) and made it permanently available to shareholders.

Dreieich, 27 February 2009

Prof. Dr. Gregor Schulz Chairman of the Management Board

Mr. Kannoh

Dr. Michael Ramroth Chief Financial Officer

### Declaration of the Board of Management in accordance with Section 37y No. 1 of the German Securities Trading Act (WpHG) in conjunction with Section 297 (2) No. 4 and Section 315 (1) No. 6 of the German Commercial Code (HGB)

"To the best of our knowledge, and in accordance with the applicable reporting principles, the Group financial statements give a true and fair view of the assets, liabilities, financial position and profit or loss of the Group, and the Group management report includes a fair review of the development and performance of the business and the position of the Group, together with a description of the principal opportunities and risks associated with the expected development of the Group."

Dreieich, 27 February 2009

**Biotest Aktiengesellschaft** 

Management Board

Prof. Dr. Gregor Schulz Chairman of the Management Board

Mr. Kannoh

Dr. Michael Ramroth Chief Financial Officer

### Auditor's report

We have audited the consolidated financial statements prepared by the Biotest Aktiengesellschaft, Dreieich, comprising the balance sheet, the income statement, statement of recognized income and expense, cash flow statement and the notes to the consolidated financial statements, together with the group management report for the business year from 1 January to 31 December 2008. The preparation of the consolidated financial statements and the group management report in accordance with IFRS, as adopted by the EU, and the additional requirements of German commercial law pursuant to Section 315a (1) of the German Commercial Code (HGB) are the responsibility of the parent company's management. Our responsibility is to express an opinion on the consolidated financial statements and on the group management report based on our audit.

We conducted our audit of the consolidated financial statements in accordance with Section 317 HGB and German generally accepted standards for the audit of financial statements promulgated by the Institut der Wirtschaftsprüfer (IDW). Those standards require that we plan and perform the audit such that misstatements materially affecting the presentation of the net assets, financial position and results of operations in the consolidated financial statements in accordance with the applicable financial reporting framework and in the group management report are detected with reasonable assurance. Knowledge of the business activities and the economic and legal environment of the Group and expectations as to possible misstatements are taken into account in the determination of audit procedures. The effectiveness of the accounting-related internal control system and the evidence supporting the disclosures in the consolidated financial statements and the group management report are examined primarily on a test basis within the framework of the audit. The audit includes assessing the annual financial statements of those entities included in consolidation, the determination of entities to be included in consolidation, the accounting and consolidation principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements and group management report. We believe that our audit provides a reasonable basis for our opinion.

Our audit has not led to any reservations.

In our opinion, based on the findings of our audit, the consolidated financial statements comply with IFRS, as adopted by the EU, the additional requirements of German commercial law pursuant to Section 315a (1) HGB and give a true and fair view of the net assets, financial position and results of operations of the Group in accordance with these requirements. The group management report is consistent with the consolidated financial statements and as a whole provides a suitable view of the Group's position and suitably presents the opportunities and risks of future development.

Frankfurt/Main, 27 February 2009

KPMG AG Wirtschaftsprüfungsgesellschaft

(formerly KPMG Deutsche Treuhand-Gesellschaft Aktiengesellschaft Wirtschaftsprüfungsgesellschaft)

Dr. Böttcher Wirtschaftsprüfer (German Public Accountant) Gottron Wirtschaftsprüfer (German Public Accountant)

# Report of the Supervisory Board

During the past financial year, the Supervisory Board fulfilled its duties in accordance with legislation, the Articles of Association and rules of procedure. The Supervisory Board carefully and regularly monitored and advised the Board of Management. The Board of Management regularly, promptly and comprehensively informed the Supervisory Board through written and oral reports concerning all issues of fundamental importance to the company, in particular those relating to planning, business development, corporate development, the risk position and risk management. Where business developments deviated from the planning, the Board of Management provided comprehensive explanations on these. The Board of Management involved the Supervisory Board in the coordination of the strategy and progress with its implementation within the company at all times.

The Supervisory Board met at six regularly convened meetings in financial year 2008. One Supervisory Board resolution was taken by written circular in lieu of a meeting. In addition to the Supervisory Board meetings, the Chairman of the Supervisory Board was regularly informed by the Chairman of the Board of Management of current business developments and major business transactions. Business transactions of major importance to the company were discussed extensively on the basis of reports by the Board of Management and the Supervisory Board was involved in decisions at an early stage. In addition to discussing the topics indicated below at Supervisory Board and committee meetings and receiving written and oral explanations from the Board of Management, the Supervisory Board receives monthly written reports on the business position and business developments. These reports also include explanations concerning any deviations from current or planned developments. Beyond this, the Chairman of the Supervisory Board automatically receives all internal audit reports as well as copies of the minutes of Board of Management meetings, which are supplied on request.

### Main focus of the Supervisory Board deliberations

Topics regularly discussed by the Supervisory Board included planning and the current business development of the company, as well as its strategic direction and financial position. An additional focal point was the further development of the Biotherapeutics segment.

At the meeting held on 19 March 2008, the Supervisory Board reviewed current business developments, discussed the annual financial statements of Biotest AG and the consolidated financial statements for financial year 2007 with the auditors, KPMG AG Wirtschaftsprüfungsgesellschaft, Frankfurt/Main, and considered individual items of the financial statements in detail. The annual financial statements of Biotest AG and the consolidated financial statements for financial year 2007 were subsequently adopted. Other items on the agenda related to approval of the Report of the Supervisory Board, appointment of the auditors for the annual financial statements for financial year 2008 and the extension of the Long Term Incentive Programme to include a third tranche. The proposal for appropriation of profits to be made at the Annual Shareholders' Meeting was also resolved. Moreover, the Supervisory Board resolved the agenda for the 2008 ordinary Shareholders' Meeting. By circular resolution of 30 April 2008, the Supervisory Board resolved to supplement its report to the Annual Shareholders' Meeting to include details regarding the report on interdependence.

Its meeting on 27 May 2008 immediately before the Annual Shareholders' Meeting served to prepare the Supervisory Board for the Annual Shareholders' Meeting and to establish a new subsidiary in Hungary.

Alongside the current business position, the Supervisory Board discussed how to secure fractionation capacity and the future supply of plasma in its meeting on 18 July 2008. The Supervisory Board approved the acquisition of a plot in Dreieich, in order to ensure that the Company has further scope for developing future plans relating to its plant structure.

In the Supervisory Board meeting held on 29 September 2008, the Board of Management provided information to the Supervisory Board regarding business performance and the interim results of the clinical trial with the BT-061 monoclonal antibody. In addition, the Board of Management provided an initial overview of future plans for the plant structure. The Supervisory Board also discussed staff development and how to promote staff loyalty. Professor Muff, who was appointed by the court as a member of the Supervisory Board prior to the meeting, was elected Chairman of the Audit Committee and therefore succeeds Dr. Hückmann.

In the meeting on 12 December 2008, a further presentation was made on current business developments. The Board of Management provided explanations on the budget for financial year 2009, which was then approved by the Supervisory Board. The Supervisory Board also approved the proposed investment plan, subject to liquidity and income being safeguarded as far as possible. The Board of Management gave a presentation to the Supervisory Board on the basic structure of risk management and the major risks to the company. At the end of the meeting, Professor Muff was elected as a new member of the Presiding Committee.

#### Committees

The Supervisory Board was supported in its work by the Presiding Committee, the Personnel Committee and the Audit Committee established by the Supervisory Board.

In addition to the regular Supervisory Board meetings, the Presiding Committee met with the Personnel Committee and the Board of Management for a joint meeting, during which the issue of a third tranche under the LIT programme was discussed alongside the achievement of the targets for financial year 2007 and the new Board of Management targets for financial year 2008. The Personnel Committee took one resolution by circular in lieu of a meeting (see below).

The Audit Committee held two meetings in 2008. At the first meeting on 17 March 2008, the Audit Committee reviewed and discussed the annual financial statements and the auditors' report on the key aspects of their work. The second meeting was convened on 28 November 2008 to discuss matters which included any issues relat-

ing to the 2008 annual financial statements, determining the key aspects of the audit and discussing the liquidity situation.

#### **Corporate Governance**

In 2008, the Supervisory Board continued to monitor the development of corporate governance standards within the company. In accordance with Section 3.10 of the German Corporate Governance Code, the Supervisory Board and the Board of Management report on corporate governance within Biotest AG appears on pages 178 to 184. In March 2009, the Board of Management and Supervisory Board of Biotest AG submitted a qualified Declaration of Compliance with the recommendations of the Government Commission on the German Corporate Governance Code pursuant to Section 161 of the Stock Corporation Act (AktG).

#### Changes in the Board of Management and Supervisory Board

No changes have taken place in the membership of the Board of Management. The Personnel Committee exclusively resolved the increase in the age limit for Professor Schulz in view of the application of change of control regulations in the Board of Management contract. The adjustment was implemented subsequently as an addendum to the Board of Management contract.

Dr. Hückmann resigned from his office as member of the Supervisory Board as of the end of the Annual Shareholders' Meeting on 27 May 2008. Since discussion regarding potential candidates was as yet ongoing at that time, the Company made an application for appointment by the district court in Offenbach of a new Supervisory Board member following conclusion of the talks. On 22 September 2008, Professor Muff was appointed by the court as a new member of the Supervisory Board.

The Chairman of the Supervisory Board thanks Dr. Hückmann for his cooperation based on trust over many years.

#### Annual financial statements and consolidated financial statements

The annual financial statements of Biotest AG and the consolidated financial statements as of 31 December 2008, as well as the management report and the Group management report have been examined by KPMG AG Wirtschaftsprüfungsgesellschaft, Frankfurt/Main, and issued with an unqualified certification. The Supervisory Board has acknowledged the results of the audit and concurs with these. The auditors' report was presented to all members of the Supervisory Board. The auditors attended the meeting of the Supervisory Board on 5 March 2009 concerning the annual financial statements and consolidated financial statements. They reported on the key findings of the audit and were also on hand to provide supplementary information. On completion of the examination, the Supervisory Board found no cause for objection. The Supervisory Board approved the annual financial statements and consolidated financial statements and consolidated financial statements were therefore adopted. The Supervisory Board endorsed the proposal of the Board of Management for appropriation of the distributable profit. Pages 85, 92 and 93 of the Group management report contain details on the important provisions which take effect in the event of a change of control. The syndicated loan agreement grants the creditor banks a right to termination in the event of a change of control. Similarly, the creditors who are party to the profit-participation certificate are entitled to terminate the agreement in the event of a change of control. The service contracts of both members of the Board of Management provide for a settlement in the event that their Board of Management contracts are prematurely terminated as a result of a change of control. For further details, we make reference to the relevant passages in the Group management report, rather than repeating these at this juncture.

#### **Report on interdependence**

The Board of Management has prepared its report on relationships with affiliated companies and submitted it to the Supervisory Board together with the related audit report provided by KPMG AG Wirtschaftsprüfungsgesellschaft, Frankfurt/Main.

The auditors issued the following unqualified certification:

"On the basis of the audit duly conducted by us and our assessment, we confirm that

- 1. the actual details provided in the report are accurate,
- 2. the transactions indicated in the report did not involve disproportionately high payments by the Company."

The auditors were present at the Supervisory Board meetings in which the report on relationships with affiliated companies was discussed and provided a presentation on the key findings of their audit.

The review of the management report and of the audit report prepared by the auditors did not give rise to objection from the Supervisory Board. The Supervisory Board endorsed the findings of the audit carried out by the auditors. On completion of its examination, the Supervisory Board found no cause for objection in relation to the declaration provided by the Board of Management at the end of the report on interdependence regarding Biotest AG's relationships with affiliated companies.

The Supervisory Board would like to express its thanks to the Board of Management and all employees for their dedication and the success of their accomplishments in financial year 2008.

Dreieich, 5 March 2009

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The Supervisory Board Dr. Thorlef Spickschen Chairman

# **Corporate Governance**

Joint report by the Board of Management and the Supervisory Board of Biotest AG pursuant to Section 3.10 of the German Corporate Governance Code

### **Corporate Governance principles**

The corporate management and control of Biotest AG are geared towards the company's long-term success. The Board of Management and the Supervisory Board work closely together and base their actions on internationally accepted standards of good corporate governance.

Corporate management and control thereof meet the valid legal guidelines and the requirements ("should" provisions) of the German Corporate Governance Code (the "Code"), unless the statement of compliance expressly indicates exception. Amended and supplemented on several occasions in recent years, the list of recommendations and suggestions of the Code represents a high standard in our view, including at international level.

### Explanations to the new version of the Code

With effect from 6 June 2008, the German Corporate Governance Code has been subject to moderate development. In addition to further clarification of Section 4.2.2, which relates to the treatment of remuneration of the Board of Management by the Supervisory Board, three previous suggestions ("may" and "can" provisions) in Section 4.2.3 have been converted into recommendations ("should" provisions). The provisions relate to payments to members of the Board of Management in the event of premature termination of Board of Management duties.

Accordingly, when Board of Management contracts are drawn up, it should be ensured that, in the event of premature termination of Board of Management duties for no major reason, payments do not exceed the value of two years' remuneration (settlement cap) and at the same time, do not provide remuneration in excess of the residual contractual term. The Code also recommends that the corresponding payment commitment in the event of a change in control amounts to a maximum of 150% of the settlement cap.

The recommendation under Section 7.1.2 is also new and states that the Supervisory Board or its Audit Committee should discuss interim financial reports with the Board of Management prior to publication.

# Implementation of the recommendations and suggestions of the Code at Biotest

The Supervisory Board and Board of Management have comprehensively addressed the recommendations and suggestions in the version of the Code dated 6 June 2008. The Boards agree that Biotest should implement the "should" (recommendations) and "can" provisions (suggestions) with one exception in each case:

We will not implement the recommendation in Section 5.3.3 regarding the establishment of a Nomination Committee within the Supervisory Board. Since the Supervisory Board of Biotest AG comprises only four shareholder representatives, we do not deem it necessary to set up a separate committee from this small group of people. Moreover, we believe that improved transparency of the selection procedure, which is the aim of the recommendation, can be achieved from within the full Supervisory Board.

For reasons of the associated cost, Biotest will dispense with the recommendation made in Section 2.3.4 to transmit the Annual Shareholders' Meeting via the Internet.

The suggestions regarding settlement regulations for members of the Board of Management, which were introduced with the amendment of the Code in June 2007 and converted into recommendations with the amendment of the Code in June 2008, have not applied to date. Biotest has not concluded any new Board of Management contracts in the relevant period.

The statement of compliance which was approved at the balance sheet meeting of the Supervisory Board on 5 March 2009 is available on the company's website (www.biotest.de).

Also available on the site are the previous declarations of compliance, the Corporate Governance report, the remuneration report and the company's Articles of Association.

### Corporate Governance in financial year 2008

The Annual Shareholders' Meeting of Biotest AG took place in Frankfurt/Main on 27 May 2008. 84.02% of the ordinary share capital was represented. The proposals made by the Board of Management were approved with a significant majority in each case. These included authorisation for the Board of Management to buy and sell treasury stock. This authorises the Board of Management to buy ordinary bearer shares and/ or preference bearer shares. At no time may the shares acquired, combined with other treasury stock of the company or shares that are attributable to the company in accordance with Sections 71a ff. of the German Stock Corporation Act (AktG), exceed 10% of the share capital existing at the time of the Annual Shareholders' Meeting, amounting to €30,025,152.00. The authorisation is valid until 26 November 2009.

The authorisation to buy treasury stock issued by resolution of the Annual Shareholders' Meeting on 3 May 2007 was revoked.

### Change in the composition of the Supervisory Board

At the end of the Annual Shareholders' Meeting for 2008, Dr. Jochen Hückmann resigned from his office. Dr. Hückmann was a member of the Supervisory Board for more than ten years and elected by the capital side.

With effect from 22 September 2008, the Supervisory Board appointed Professor Dr. Marbod Muff, resident in Ingelheim/Rhine, to the Supervisory Board as a new member. He will also assume the duties of Dr. Hückmann as Chairman of the Audit Committee. Until 31 December 2008, Professor Muff was a member of the management of Boehringer Ingelheim GmbH with responsibility for Finance and Human Resources.

The term of office of all Supervisory Board members runs until the end of the Annual Shareholders' Meeting, which grants formal approval of the Supervisory Board's actions for financial year 2011.

Professor Muff is currently court-appointed. During the Annual Shareholders' Meeting of 7 May 2009, a vote will therefore be taken on whether to terminate Professor Muff's term of office with effect from the end of the Annual Shareholders' Meeting. This would result in the release of the Supervisory Board in financial year 2011, which would ensure that the terms of office of the shareholder representatives on the Supervisory Board are synchronised.

The Board of Management has lodged an appeal against the decision of the Frankfurt/ Main Higher Regional Court of 12 February 2008, whose ruling upheld the complaint against the resolution of the 2006 Annual Shareholders' Meeting to amend the Articles of Association of Biotest AG. The Federal High Court of Justice in Germany will make a decision on the matter in the last instance. The date for the hearing has yet to be set.

The contested resolution regards the right granted to the Chairman of the Annual Shareholders' Meeting to restrict the right of shareholders to speak and raise questions at the Annual Shareholders' Meeting. With the amendment, Biotest AG implemented the provisions of the Act on Corporate Integrity and the Modernisation of the Right to Appeal (UMAG). For further information on this matter, please refer to the Corporate Governance report in the 2007 Annual Report.

### **Directors' Dealings**

The following purchases and sales subject to notification by members of the executive bodies and other senior management members at the Biotest Group took place in financial year 2008:

				Number of				
Name	Function	ISIN	Share class	Purchase/sale	Trade date	shares	€ price	€ value
Dr. Michael Ramroth	Executive Body	522721/ DE000522723	Biotest preference share	Purchase	19 Dec 2008	500	42.28	21,140.00

# Remuneration of the Board of Management and the Supervisory Board

Joint report by the Board of Management and the Supervisory Board of Biotest AG as part of the Corporate Governance report

## Remuneration of the Board of Management

The Supervisory Board specifies the remuneration for members of the Board of Management. This is composed of a fixed remuneration, a bonus and a component entailing a long-term incentive effect and risk elements. Added to this are benefits in kind. From the point of view of the Supervisory Board, all remuneration components are appropriate, individually and as a whole.

Pursuant to Section 4.2.3 of the Code, the remuneration of the Board of Management including the non-monetary components is presented in detail below.

#### **Fixed remuneration**

The non-performance related fixed remuneration of members of the Board of Management is composed of their fixed salary and fringe benefits. The amount is based on Biotest's financial situation and future prospects and on remuneration in the competitive environment.

The annual fixed salary is specified for the entire term of the respective contract of employment and paid in 13 monthly instalments. In the past financial year, the fixed salary of Professor Schulz amounted to  $\leq$ 300 thousand, while that of Dr. Ramroth amounted to  $\leq$ 260 thousand.

Members of the Board of Management received fringe benefits above and beyond their fixed salary.

#### **Insurance policies**

Both members of the Board of Management are insured professionally and privately as part of Biotest AG's collective accident policy. Members of the Board of Management receive an allowance for social insurance and also for direct insurance. In 2008, the value of these benefits amounted to €27 thousand for Professor Schulz and €24 thousand for Dr. Ramroth. The members of the Board of Management of Biotest AG are covered by the Groupwide D&O insurance with excess, which Biotest has concluded for its entire senior management.

#### Further benefits in kind

Both members of the Board of Management are provided with a top-of-the-range company car free of charge, which may also be used privately. The value of the benefits in kind in 2008 amounted to  $\in$ 8 thousand for Professor Schulz and  $\in$ 8 thousand for Dr. Ramroth.

The Board of Management of Biotest AG is also included in Biotest AG's occupational pension scheme. The members receive an individual commitment as part of Biotest AG's pension scheme, for which provisions are created. The amount of the provisions for this type of pension scheme is contingent on the number of years worked, the eligible salary and the benefits scale applicable below and above the social contribution assessment limit.

No loans or advances were granted to members of the Board of Management in financial year 2008.

#### **Bonuses**

The performance-related component of the remuneration (bonuses) is based on the achievement of corporate and personal targets. The operating profit (EBIT) and return on capital employed (RoCE) are weighted at 30% each and the achievement of individual targets established in the previous financial year at 40%. A separate bonus for the achievement of targets of particular significance can also be determined by the Presiding Committee of the Supervisory Board.

The individual targets are agreed annually between members of the Board of Management and the Presiding Committee of the Supervisory Board. The latter determines the level of the performance-related component after the end of the financial year.

For 2008, a provision of €150 thousand was created for the performance-related remuneration of Professor Schulz and a provision of €130 thousand for Dr. Ramroth.

Each member of the Board of Management received a bonus of €100 thousand (gross) for the successful establishment and integration of Biotest Pharmaceuticals Corp. in the Biotest Group, which was paid in instalments of €50 thousand in January and July 2008. Provisions for these amounts were included in the 2007 annual financial statements.

Remuneration in 2008 comprising the components fixed salary, bonuses and benefits in kind totalled  $\leq$ 485 thousand for Professor Schulz and  $\leq$ 422 thousand for Dr. Ramroth.

#### Remuneration component with a long-term incentive effect and risk elements

The remuneration component with a long-term incentive effect and risk elements is based on Biotest's Long Term Incentive Programme (LTIP). In addition to the members of the Board of Management, this also includes selected senior managers, who have a profound influence on the company's success through their position within the Group, their decisions, their management and their actions.

The programme's structure is geared to the established criteria which the capital market sets for systems of this kind, and complies with the requirements of the Code.

The first tranche of the programme was launched on 1 October 2006 and ended on 31 December 2008, with a second tranche beginning on 20 June 2007 and ending on 31 December 2009 and a third tranche starting on 1 May 2008, which will run until 31 December 2010.

The precondition for participation is the participant's own investment through the purchase of preference shares in Biotest AG. The maximum number of preference shares that members of the Board of Management can purchase is 1,000. The shares must be held in a securities account at least until the incentive total is disbursed.

The level of the incentive payment is calculated from the performance of Biotest preference shares compared to the SDAX selection index and from the average EBIT margin achieved during the term of the relevant tranche (2006 to 2008, 2007 to 2009 and 2008 to 2010). Section F1 of the notes to the consolidated financial statements provides a detailed explanation of the procedure used to calculate the incentive payment.

It is anticipated that participants will be paid the incentive component in May of the year, following expiry of the tranche.

The total value of the LTIP over the entire period amounted to  $\leq$ 494 thousand for Professor Schulz and  $\leq$ 442 thousand for Dr. Ramroth as of the valuation date of 31 December 2008.

In financial year 2008, Biotest transferred a total of €194 thousand to pension reserves for the Board of Management. Of this figure, €152 thousand was attributable to Professor Schulz and €42 thousand to Dr. Ramroth.

# Remuneration system for former members of the Board of Management and their surviving dependants

The pensions agreed in their service contracts are paid to former Board of Management members and their surviving dependants. A total of  $\in$ 3,782 thousand is provided for this purpose. The value of pension commitments is calculated pursuant to IAS 26.

## Remuneration of the Supervisory Board

The remuneration of the Supervisory Board is regulated in the Articles of Association. Members receive an annual fixed remuneration of €15 thousand each. The Chairman of the Supervisory Board shall receive twice this amount and his Deputy one and a half times. For work in a Supervisory Board committee, a member will receive a further €3 thousand, while the Chairman of the committee will receive a further €5 thousand. Biotest AG reimburses the VAT payable on the Supervisory Board remuneration.

Furthermore, the members of the Supervisory Board receive a variable remuneration of €500 for every €1million by which the operating profit (EBIT) exceeds a minimum amount of currently €17.3 million, however, no more than a total of €5 thousand.

Like the members of the Board of Management, the members of the Supervisory Board of Biotest AG are included in the Group-wide D&O insurance with excess. Biotest paid the relevant premiums for all Supervisory Board members. No further benefits in kind were granted.

€ thousand	Fixed remuneration	Variable remuneration	Total remuneration
Dr. Thorlef Spickschen(Chairman	) 43	5	48
Dr. Cathrin Schleussner (Deputy Chairwoman)	29	5	34
Prof. Dr. Marbod Muff <sup>2)</sup>	6	2	8
Dr. Jochen Hückmann <sup>1)</sup>	9	2	11
Thomas Jakob	18	5	23
Barbara Arnold-Schlosser	18	5	23
Astrid Paluch	15	5	20
Total	138	29	167

1) as of 27 May 2008

2) as of 22 September 2008

The remuneration of the Supervisory Board was adjusted in line with the provisions of the Code by resolution of the 2008 Annual Shareholders' Meeting becoming effective from 1 January 2009.

## Glossary Technical terms

#### **ACR 70**

Set of criteria developed by the American College of Rheumatology (ACR) to assess the efficacy of treatments for rheumatologic conditions. An ACR70 response (ACR 70) is defined as 70% improvement of defined symptoms, such as joint pain, joint swelling or function impairment.

#### Aerob / Anaerob

All life processes requiring oxygen are aerobic (e.g. breathing). The opposite are anaerobic processes.

#### Albumin (or human albumin)

Protein produced in the liver which regulates and maintains the protein balance in the vascular system, as well as binding and transporting various plasma components.

#### Antigen

Molecule that is recognised by the immune system. The immune system can differentiate between "foreign" and "self" and trigger defence mechanisms, where appropriate.

#### Antibody

Antibodies are substances that are produced by the body against attack by a foreign invading substance (antigen).

#### Autoimmune disease / Autoaggression

Activity of the immune system directed against the patient's own body.

#### **Biopharmaceuticals**

Biotechnologically manufactured drugs.

#### **CE certification**

The CE mark is the manufacturer's confirmation of the product's compliance with the applicable directives of the European Union.

#### **Coagulation factors**

Proteins responsible for the blood coagulation. The 13 different factors are labelled with the Roman numerals I to XIII.

#### Congenital

Existing or acquired at birth.

#### **Consistency batch**

Batches produced as part of the drug approval process. They are used to determine whether the product retains its features in mass production and after a certain storage period.

#### Chromatography

Chemical process for separating mixtures into their components.

#### Chronic lymphocytic leukaemia

The most common form of leukaemia in the West. Unlike acute leukaemia, the disease develops over a long period of time. There is a clonal increase in B lymphocytes (white blood cells).

#### Cytokine

Sugar-containing protein with regulating functions for the growth and the differentiation of the body cells.

#### **Cytomegalovirus**

Viral infection which is generally harmless. However, if occurring in pregnancy it can cause severe foetal damage.

#### Fibromyalgia

Chronic non-inflammatory disease presenting with extensive pain affecting the muscles and tendons.

#### Filter aid procedure

Fractionation procedure for blood plasma. Plasma components are separated using special filters.

#### Fractionation

Physical separation of substance mixes (for example, blood plasma).

#### Good Manufacturing Practice (GMP)

Regulations on the safety and quality in manufacturing pharmaceutical preparations and diagnostic products.

#### Haematology

Branch of medicine concerned with blood and blood disorders.

#### Haemophilia

A blood clotting disorder resulting from defective or missing coagulation factors VIII or IX (type A or B haemophilia).

#### Hyperimmunoglobulins

Highly-enriched antibodies against special antigens.

#### IgM concentrate

Concentrated immunoglobulin M (IgM). IgM is an antibody molecule consisting of five Y-shaped sub-components. As an immunoglobulin produced only as part of an immune system response, IgM has the function of activating the complement system.

#### Immunoglobulins

Protein molecules (antibodies) that make up part of the body's immune system. Polyvalent immunoglobulins are effective against a broad spectrum of infections and hyperimmunoglobulins are effective against special antigens.

#### Immunomodulation

Modulation of the immune system with the aim of avoiding undesired reactions without affecting the defence functions as a whole.

#### Immunology

The science of the defence mechanisms of the body against alien substances and pathogens, as well as of the deficiencies of these defence mechanisms.

#### Immunosuppressed

The artificial suppression of the body's resistance to disease, for example, after transplants.

#### Immune system

The sum of all factors responsible for the body's defence against infections and invading foreign substances.

#### Indication

Condition for which an active ingredient/drug can be developed and approved.

#### Intramuscular application (IM)

Administering a drug by injecting it into a muscle.

#### Intravenous application (IV)

Administering a drug by injecting into a vein.

#### In vitro

Procedure that takes place in a laboratory setting, for example, in a test tube.

#### In vivo

Processes that take place in the body.

#### Lymphoma

General term for lymph node swelling as well as for benign and malignant tumours of the lymph tissue.

#### Monoclonal antibodies (mAb)

Antibodies that can be traced back to a single originator cell. Antibodies attach themselves to particular antigens.

#### Multiple myeloma

Malignant plasma cell growth in the bone marrow.

#### Mutual Recognition Procedure (MR Procedure)

European mutual recognition procedure by which, once national approval has been granted, product registration can be sought in other EU countries.

#### **Nanometer filtration**

Pressurised membrane filtration procedure which separates out particles in the nanometer range. Procedure used in the production of plasma proteins as an additional security step.

#### **Orphan Drug Status**

Orphan drug status is given to drugs for which there is a high medical need, but which cannot be developed without subsidies, due to the prohibitive cost or low market potential.

#### Paul-Ehrlich-Institut (PEI)

German federal authority for sera and vaccines. The PEI is responsible for the authorisation of clinical trials and approval processes.

#### Plasma Protein Therapeutics Association (PPTA)

Association of the world's leading manufacturers of plasma proteins.

#### Plasmapheresis

Generation of plasma from blood donations. The cellular elements are immediately reinfused to the donor. What remains is blood plasma, a clear, yellowish liquid which contains the soluble proteins of the blood and minerals.

#### Polymerase chain reaction (PCR)

Method used to reproduce the genetic material, DNA, in vitro.

**Primary humoral immunodeficiency** Congenital defect of the immune system.

#### **Psoriasis**

Scaly patches. Chronic skin disease.

#### **Prions**

Proteins that are present in the human and animal body, both in normal and pathogenic structures.

#### Reagents

Substances used to test for the presence of and identify another substance.

#### Recombinant

Recombinant proteins are produced with the aid of genetically modified micro-organisms or cell lines.

#### Rheumatoid arthritis

Inflammation of the joints.

#### Serology

Sub-field within immunology which studies the reactions of antigens and antibodies (in vitro).

#### Subcutaneous application (SC)

Administering a drug by injecting it beneath the skin.

#### Substitution therapy

Medicinal use of a substance that is not being produced sufficiently by the body itself.

#### Systemic lupus erythematosus

Autoimmune disease which often starts with a fever; patients frequently experience joint pain similar to rheumatism. Erythema (redness of the skin due to dilation of the capillaries) occurs.

#### Test serum

Substance used to determine the Rhesus factor.

#### **TNF-alpha**

Abbreviation for tumour necrosis factor-alpha. The substance is controlling the body's inflammation reactions. Likely to be involved in the joint destruction process in the case of rheumatic illnesses.

#### T-regs (T regulatory cells)

Cells regulating the TNF activity.

#### Typing

Determination of individual characteristics of blood or somatic cells.

## **Glossary** Financial terms

#### **Associated company**

Group company under significant influence of the parent company.

#### At equity valuation

Accounting method for the consolidation of associated companies.

#### **Cash flow**

Actual flows of cash in a period (inflows and outflows). It is an indicator of the internal financing ability of a company.

#### **Collateral trust agreement**

Contract through which a trustee obtains securities, which he holds and manages in favour of several creditors.

#### **Currency option transactions**

Transactions which are used to hedge against risks from exchange rate fluctuations. The buyer of a currency option contract acquires the right, however not the obligation, to buy or sell a currency at a specific exchange rate on a specified date.

#### **Currency forward**

Binding agreement to exchange one currency for another on a specific date at a specified rate.

#### **Deferred taxes**

Income taxes payable or receivable in the future, which do not yet constitute actual receivables or liabilities at the time relating to the balance sheet concerned.

#### **Derivative financial instrument**

A financial instrument which is generally priced in relation to a market-based reference value.

#### EBIT

Earnings before interest and tax.

#### EBITDA

Earnings before interest, tax, depreciation and amortisation.

# Financial Assets at Fair Value through Profit or Loss (FAFVtPL)

A financial instrument category in accordance with IFRS 7.

#### Financial Assets Held for Trading (FAHfT)

A financial instrument category in accordance with IFRS 7.

#### Financial Liabilities at Amortised Cost (FLAC)

A financial instrument category in accordance with IFRS 7.

#### Financial Liabilities Held for Trading (FLHfT)

A financial instrument category in accordance with IFRS 7.

#### "First in first out"

Valuation method. Principle: assets that were produced or bought first are being sold first.

#### Forward rate (Forward interest rate)

Interest rate for a future period, which can be hedged risk-free with bonds available in the market at present.

#### **Functional currency**

Currency of the market, in which a company is mainly active.

#### Hedge accounting

Accounting technique. The establishment of hedging relationships between underlying transactions and derivative financial instruments used for hedging purposes.

#### Held to Maturity (HtM)

A financial instrument category in accordance with IFRS 7.

#### Impairment test

A test used to check the value of an item.

#### Interest rate cap

Definition of an upper and/or lower interest rate limit for a floating rate.

#### Loans and Receivables (LaR)

A financial instrument category in accordance with IFRS 7.

#### **Purchase Price Allocation (PPA)**

Allocation of the cost of purchase of a company share to the assets and debts thereby acquired.

#### Swap

Exchange transaction. Both contractual parties undertake to pay either a fixed or floating rate on a specific nominal value to the respective other party.

#### **Profit participation rights**

Upon conclusion of the profit-sharing agreement, the beneficiary undertakes to make the profit-sharing capital available to the issuer of the profit participation rights. In turn, rights to assets are made available to the beneficiary, to which as a rule shareholders of the issuer are also entitled, such as performance-related pay, a share in the liquidation proceeds or option rights.

#### Sensitivity analysis

Used to determine the impact of specific factors on certain performance indicators.

Working capital Short-term tied-up capital.

# Acknowledgements

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The annual report contains forward-looking statements on overall economic development as well as on the business, earnings, financial and asset situation of Biotest AG and its subsidiaries. These statements are based on current plans, estimates, forecasts and expectations of the company and thus are subject to risks and elements of uncertainty that could result in deviation of actual developments from expected developments. The forward-looking statements are only valid at the time of publication of this annual report. Biotest does not intend to update the forward-looking statements and assumes no obligation to do so. The English translation of the Biotest Group annual report is provided for convenience only. The German original is definitive.

# **Financial calendar**

7 May 2009	Annual General Meeting
15 May 2009	Quarterly report for Q1 2009
12 August 2009	Quarterly report for Q2 2009
5 November 2009	Quarterly report for Q3 2009
5 November 2009	Autumn Analysts and Press Conference



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